Augmentation Mammoplasty

Instructions
This is a document that has been prepared to help inform you about augmentation mammoplasty, 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
Augmentation mammoplasty is a surgical operation performed to enlarge the breast contour. The procedure is performed for a number of reasons:

- To enhance the self-concept of a woman who for personal reasons feels that her breast size is inadequate
- To correct a loss in breast volume after pregnancy
- To balance breast size, when there exists a significant difference between the size of breast

The shape and size of the breast prior to surgery will influence both the recommended treatment and the final results. If the breasts are not the same size before surgery, it’s unlikely that they will be the symmetrical afterward.

Breast contour enlargement is accomplished by inserting an implant either behind the breast tissue alone or under the breast chest muscle. Incisions are made to keep scars as 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 be influenced by your preferences, your anatomy and your surgeon’s recommendation.

Alternative Treatment
Augmentation mammoplasty is an elective surgical operation. Alternative treatment would consist of not undergoing the surgical procedure, the use of external breast prostheses or padding, or the transfer of other body tissues to enlarge breast size.

Risk of Augmentation Mammoplasty Surgery
Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with augmentation mammoplasty. Additional information may be obtained from the FDA, package insert sheets supplied by the implant manufacturer, or other information pamphlets.

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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 plastic surgeon to make sure you understand the risks, potential complications and consequences of breast augmentation.

**Bleeding** – It is possible, although unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require surgical treatment to drain accumulated blood. Do not take any 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. Should an infection occur, treatment including antibiotics, possible removal of the implant or additional surgery may be necessary. It is extremely rare that an infection would occur around the implant from a bacterial infection elsewhere in the body, but the presence of another infection increases the risk and would require rescheduling your procedure.

**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 breast can occur soon after surgery or years later. Although the occurrence of symptomatic capsular contracture is not predictable, it generally occurs in less than 15% of patients. 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. 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 and is not an accepted treatment.

**Change in nipple and skin** – Breast are usually sore after surgery. 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 color than surrounding skin. Additional surgery may be needed to treat abnormal scarring after surgery.

**Implants** – Breast implants, similar to other medical devices, can fail. Implants can break or leak. When a saline-filled implant deflates, its salt water filling will be absorbed by the body. Rupture can occur as a result of 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 do not have a definite lifespan but many will eventually require replacement or additional surgery.

**Mammography** – If you are over 35 years of age, pre-operative mammography is recommended. Post-operative mammography is preformed according to American Cancer Society guidelines. Breast implants may make mammography more difficult but no evidence exists that implants obscure the detection of breast cancer. Implant rupture infrequently occurs from breast compression during mammography. Inform your radiologist of the presences of breast implants 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).

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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. There is no medical evidence suggesting health problems for mothers or their babies with breast feeding following augmentation. Further evaluation is ongoing, but at present the practice is considered safe.

Calcification – Calcium deposits can form in the tissue surrounding the implant and may cause pain, firmness and 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 consistent with disease 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 postulated in medical literature. To date, there is no scientific evidence that woman with silicone gel-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 individual 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, both gel-filled and saline-filled devices have a silicone outer envelope. An increased risk of autoimmune disease is possible even from saline implants. Reliable medical laboratory test to determine antibodies to silicone do not exist. It has been proven that there is a relationship between silicone antibodies and diseases in woman with breast implants. Currently, there is insufficient evidence to state that there is a health benefit from removing implant(s) and scar tissue capsule(s) should an immune system disease occur.

In very few women who have breast implants, a variety of other symptoms and conditions have been reported, suggestive of an autoimmune 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 demonstrated. Because such disease states are rare, they are difficult to research. There is possibility of as yet unknown risks associated with silicone breast implants.

Unusual activities and occupations – Activities and occupations which have the potential for trauma to the breast could potentially break or damage breast implants.

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

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Breast disease – Current medical information does not demonstrate an increased or decreased risk of breast disease or breast cancer in women who have breast implant surgery. Breast disease occurs independently of breast implants. It is recommended that all women perform periodic self-examinations of their breasts, have mammography according to American Cancer Society guidelines, and to seek professional care should they recognize any change or abnormality.

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**Additional Surgery**
Should complications occur, additional surgery or other treatments may be necessary.

**Health Insurance**
Most health insurance companies excluded coverage for cosmetic surgical operations such as abdominoplasty or any complications that may occur from surgery. Please carefully review your health insurance subscriber-information pamphlet for specific coverage exclusions.

**Financial Responsibility**
The cost of surgery involves several charges. The total cost includes fees charged by your surgeon, anesthesia, laboratory test and outpatient facility charges. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductible and charges not covered. Additional costs may occur should complications develop from the surgery. Secondary surgery charges involved with revisionary procedures would also be your responsibility.

**Disclaimer**
Informed consent documents are used to communicate information about the proposed surgical treatments of the disease or condition along with disclosing the risks and noting alternative forms of treatment. The informed consent process attempts to define principles of risk and 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 or risks encountered. Your plastic 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 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 our questions answered prior to proceeding with surgery.*

**Patient Initials:** __________