

## **Inherent Surgical Risk of Breast Implant Surgery:**

**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 blood transfusion. Intra-operative blood transfusion may also be required. Hematoma may contribute to capsular contracture, infection or other problems. Do not take any aspirin or anti-inflammatory medications for ten days before or after surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. Hematoma can occur at any time following injury to the breast. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS).

**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. This may contribute to infection, capsular contracture, or other problems.

**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. 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 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. In extremely rare instances, life-threatening infections, including toxic shock syndrome have been noted after breast implant surgery. Individuals with an active infection in their body or weakened immune system should not undergo breast augmentation.

**Scarring**- All surgery leaves scars, some more visible than others. Excessive scarring is uncommon. 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 color 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. In some cases scars may require surgical revision or treatment.

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

**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 to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

**Change in Nipple and Skin Sensation**- You may experience a diminished (or loss) of sensitivity of the nipples and the skin of your breast. Partial or permanent loss of nipple and skin sensation may occur. Changes in sensation may affect sexual response or the ability to breast feed a baby.

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

**Pain**- You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after breast implant surgery. Pain may be the result of improper implant size, placement, surgical technique, capsular contracture, or sensory nerve entrapment or injury.

Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

**Skin Discoloration / Swelling**- Some bruising and swelling normally occurs after breast augmentation. 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.

**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 removal.

**Damage to Deeper Structures**- There is the potential for injury to deeper structures including nerves, blood vessels and muscles and lungs (pneumothorax) during this 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.

**Delayed Healing**- Wound disruption or delayed wound healing is possible. Some areas of the breast skin or nipple region may not heal normally and may take a long time to heal. Areas of skin or nipple tissue may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Individuals who have decreased blood supply to breast tissue from past surgery or radiation therapy may be at increased risk for wound healing and poor surgical outcome. **Smokers have a greater risk of skin loss and wound healing complications.**

**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 anesthesia. 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. It is important to discuss with your physician 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 anesthesia, even in patients without symptoms. Should any of these complications occur, you may require hospitalization and additional treatment. If you experience after surgery shortness of breath, chest pain, or unusual heart beats, you should have this evaluated immediately

**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.

### **Additional Breast Implant Advisory Information:**

**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 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, have mammography according to American Cancer Society guidelines, and to seek professional care should a breast lump be detected. Care must be exercised during breast biopsy procedures to avoid damaging the breast implant.

**Mammography**- Breast implants may make mammography more difficult and may obscure the detection of breast cancer. Any breast implant can impair the detection of breast cancer, regardless of the type of implant or where it is placed in relation to the breast. 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. Patients may wish to undergo a preoperative mammogram and another one after implantation to establish a baseline view of their breast tissue. You may be advised to undergo a MRI study in the future to verify the condition of your breast implants inside your body.

**Second-Generation Effects**- A review of the published medical literature regarding potential damaging effect on children born of mothers with breast implants is insufficient to draw definitive conclusions that this represents a problem.

**Long Term Results**- Subsequent alterations in breast shape may occur as the result of aging, weight loss, weight gain, pregnancy, menopause, or other circumstances not related to your augmentation mammoplasty. Breast sagginess may normally occur.

**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 implant placement, displacement, nipple location, unanticipated breast shape and size, loss of function, 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, change implant size or remove and not replace implants.

**Removal / Replacement of Breast Implants**- Future revision, removal, or replacement of breast implants and the surrounding scar tissue envelope involves surgical procedures with risks and potential complications. There may be an unacceptable appearance of the breasts following removal of the implant.

**Capsule Squeeze Procedures**- Closed capsulotomy, the process of forcefully squeezing the fibrous capsule around a breast implant to break up scarring is not recommended. This may result in rupture of the breast implant, gel migration, bleeding, or other complications.

**Immune System Diseases and Unknown Risks**- A small number of 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, after several large epidemiological studies of women with and without implants, there is no scientific evidence that women with either saline-filled or silicone gel-filled breast implants have an increased risk of these diseases. These diseases appear no more common in women with implants than those women without implants. The effect of breast implants in individuals with pre-existing immune system and connective-tissue disorders is unknown. There is the possibility of unknown risks associated with silicone breast implants and tissue expanders.

**Breast and Nipple Piercing Procedures**- Individuals with breast implants seeking to undergo body piercing procedures to the breast region must consider the possibility that an infection could develop anytime following this procedure. Should an infection occur, it is possible that it could spread to the breast implant space. 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. Individuals who currently

wear body piercing jewelry in the breast region are advised that a breast infection could also develop from this activity

**Interference with Sentinel Lymph Node Mapping Procedures-** Breast augmentation procedures (periareolar- transmammary) that involve cutting through breast tissue, similar to a breast biopsy in order to place breast implants, can potentially interfere with diagnostic procedures to determine lymph node drainage of breast tissue to stage breast cancer. If this is a concern, individuals considering breast augmentation by these approaches may elect to consider another surgical approach (inframammary or standard periareolar).

**Large Volume Breast Augmentation-** Patients who request an outcome of augmentation mammoplasty that produces disproportionately large breast size must consider that such a choice can place them at risk for a less than optimal long term outcome and the need for re-operation and additional expenses. The placement of excessively-sized breast implants exceeds the normal dimensions of the breast, produce irreversible tissue thinning, implant drop out, and visible/palpable rippling.

**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 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.

**Female Patient Information-**It is important to inform your plastic surgeon if you use of birth control pills, estrogen replacement, or if you suspect that you are pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

**Medications-** There are potential adverse reactions that occur as the result of taking over the counter, herbal, and/or prescription medications. Be sure to check with your physician about 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.

**Breast Implant Technology / Technologic Improvements in Breast Implants-** The technology of breast implant design, development and manufacture will continue to progress and improve. Newer generations of implants which may be better in some way from currently available ones may be developed in the future.

**Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray)-** Patients who are currently smoking, use tobacco products, or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying and delayed healing. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smokers may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication.

**ADDITIONAL SURGERY NECESSARY (Re-operations)-**

There are many variable conditions that may influence the long term result of breast augmentation surgery. It is unknown how your breast tissue may respond to implants or how wound healing will occur after surgery. Secondary surgery may be necessary at some unknown time in the future to replace your breast implants or to improve the outcome of breast augmentation surgery. You may elect to or be advised to have your breast implants removed and not replaced in the future. 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 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. In some situations, it may not be possible to achieve optimal results with a single surgical procedure.

**Patient Compliance-** Follow all physician 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 around implants and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.