

# INFORMED CONSENT – PLACEMENT OF A TISSUE EXPANDER

## **INSTRUCTIONS**

This is an informed-consent document that has been prepared to help inform you about placement of a tissue expander for reconstruction, its risks, as well as alternative treatment(s).

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 plastic surgeon and agreed upon by you.

## **GENERAL INFORMATION**

Tissue expansion is used in reconstructive surgery for the treatment of a variety of problems in both children and adults. It is used in reconstruction in instances where there is not enough adjacent tissue to close a defect primarily or to repair with a local flap. Expansion is also indicated when repair of a defect by an alternative method such as a local, regional, or distant flap will result in an unacceptable donor or recipient site deformity.

## **ALTERNATIVE TREATMENTS**

Scar revision and serial excision are alternative treatment methods. Risks and potential complications are also associated with alternative surgical forms of treatment.

## **RISKS OF TISSUE EXPANDER 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 placing a tissue expander.

**Tissue Expander / Implants-** Tissue expanders and implants, similar to other medical devices, can fail. Tissue expanders and implants can break or leak. When a saline-filled implant or tissue expander ruptures, the body absorbs the saline material, but the shell material remains. Rupture can occur because of an injury or from no apparent cause (silent rupture). It is possible to damage a tissue expander or implant at the time of surgery or subsequently with a needle during the insertion of saline into the device. Damaged, leaking, or broken tissue expanders and implants cannot be repaired and require replacement or removal. Tissue expanders can wear out, they are not guaranteed to last a lifetime and future surgery may be required to replace one or both implants. A MRI (magnetic resonance imaging) study may be necessary to evaluate the possibility of device rupture or deflation, yet may not be 100% accurate in diagnosing integrity.

**Implant Extrusion / Tissue Necrosis-** Lack of adequate tissue coverage or infection may result in exposure and extrusion of the tissue expander or implant through the skin. Tissue breakdown (necrosis) has been reported with the use of steroid drugs, after chemotherapy/radiation to breast tissue, due to smoking, microwave diathermy, and excessive heat or cold therapy. In some cases, incision sites fail to heal normally. A tissue expander or implant may become visible at the surface of the breast as a result of the device pushing through layers of skin. If tissue breakdown occurs and the tissue expander or implant becomes exposed, removal may be necessary. Permanent scar deformity may occur.

**Implant Displacement and Tissue Stretching-** Displacement, rotation, or migration of a breast implant or tissue expander may occur from its initial placement and can be accompanied by discomfort and/or distortion in breast shape (visible rippling of the skin). Unusual techniques of placement may increase the risk of displacement or migration. Additional surgery may be necessary to attempt to correct this problem. It may not be possible to resolve this problem once it has occurred.

**Surface Contamination** - Skin oil, lint from surgical drapes, or talc may become deposited on the surface of the tissue expander or implant at the time of insertion. The consequences of this are unknown.

**Unusual Activities and Occupations-** Activities and occupations that have the potential for trauma to the breast could potentially break or damage a tissue expander or implant, or cause bleeding/seroma.

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**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). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

**Seroma**- Fluid may accumulate around the tissue expander following surgery, trauma or vigorous exercise. Additional treatment may be necessary to drain fluid accumulation around tissue expander or implant. This may contribute to infection, capsular contracture, or other problems.

**Infection**- Although 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 tissue expander or implant. Subacute or chronic infections may be difficult to diagnose. Should an infection occur, treatment including antibiotics, possible removal of the expander/implant, or additional surgery may be necessary. Infections with the presence of a tissue expander/implant are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the device may have to be removed. It is extremely rare that an infection would occur around an implant or expander 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 tissue expander and breast implant surgery. Individuals with a active infection in their body or weakened immune system (currently receiving chemotherapy or drugs to suppress the immune system), may be at greater risk for infection.

**Change in Skin Sensation**- It is common to experience diminished (or loss) of skin sensation in areas that have had surgery. Diminished (or complete loss of skin sensation) may not totally resolve. Changes in sensation may affect sexual response or the ability to breast feed a baby.

**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.

**Major Wound Separation**- Wounds may separate after surgery. Should this occur, additional treatment including surgery may be necessary.

**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.

**Skin Discoloration / 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.

**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.

**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 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.

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**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.

**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.

**Delayed Healing-** Wound disruption or delayed wound healing is possible. Some areas of the skin may not heal normally and may take a long time to heal. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Individuals who have decreased blood supply to 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.**

**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.

**Asymmetry-** Symmetrical body appearance may not result after surgery. Factors such as skin tone, fatty deposits, skeletal prominence, and muscle tone may contribute to normal asymmetry in body features. Most patients have differences between the right and left side of their body before any surgery is performed. Additional surgery may be necessary to attempt to improve asymmetry.

**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.

**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. 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.

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

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

**Surgical Wetting Solutions-** There is the possibility that large volumes of fluid containing dilute local anesthetic drugs and epinephrine that is injected into fatty deposits during surgery may contribute to fluid overload or systemic reaction to these medications. Additional treatment including hospitalization may be necessary.

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**Persistent Swelling (Lymphedema)**- Persistent swelling in the legs can occur following surgery.

**Other**- You may be disappointed with the results of surgery. Infrequently, it is necessary to perform additional surgery to improve your results. You may not be able to achieve adequate fullness in your breasts without needing to wear support garments.

### **Additional Advisories**

**Disease**- Cancer can occur independently of surgery. Individuals with a personal history or family history of cancer may be at a higher risk of breast cancer than someone 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 seek professional care should a breast lump be detected.

**Long-Term Results**- Subsequent alterations in the appearance of your body may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause or other circumstances not related to your 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, unanticipated shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Size may be incorrect. Unsatisfactory surgical scar location or appearance may occur. It may be necessary to perform additional surgery to improve your results.

### **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 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 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. 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.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired.

**Female Patient Information**- It is important to inform your plastic surgeon if you use birth control pills, 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.

**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 physician states it is safe.

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**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.

### **ADDITIONAL SURGERY NECESSARY (Re-Operations)**

There are many variable conditions that may influence the long-term result of mastopexy surgery. It is unknown how your breast tissue may respond or how wound healing will occur after 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 mastopexy 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 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.

### **HEALTH INSURANCE**

Most health insurance companies exclude coverage for cosmetic surgical operations such as a mastopexy or any complications that might occur from surgery. Please carefully review your health insurance subscriber-information pamphlet. **Most insurance plans exclude coverage for secondary or revisionary surgery due to complications of cosmetic surgery.**

### **FINANCIAL RESPONSIBILITIES**

The cost of surgery involves several charges for the services provided. The total includes fees charged by your surgeon, 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. 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. **In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.**

### **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.

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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 which 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.**

# CONSENT FOR SURGERY / PROCEDURE or TREATMENT

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

## Placement of a tissue expander for reconstruction

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 anesthesia, 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 judgment 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 anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.
5. I consent to be photographed or televised before, during, and after 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. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices or body parts that may be removed.
8. 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.
9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
11. I realize that not having the operation is an option.
12. IT 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 (1-12). I AM SATISFIED WITH THE EXPLANATION.

\_\_\_\_\_  
Patient or Person Authorized to Sign for Patient

Date \_\_\_\_\_ Witness \_\_\_\_\_