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CONSENT FOR 1ST STAGE BREAST RECONSTRUCTION WITH TISSUE EXPANDERS OR DIRECT-TO-IMPLANTS SURGERY

There is a variety of surgical techniques for breast reconstruction. Breast cancer patients who are medically appropriate for breast reconstruction may consider tissue expander breast reconstruction, either immediately following mastectomy or at a later time. The best candidates, however, are women whose breast cancer, as far as can be determined, seems to be eliminated by mastectomy and other treatments.

Breast reconstruction has no known effect on altering the natural history of breast cancer or interfering with other forms of breast cancer treatment such as chemotherapy or radiation.

Breast reconstruction with tissue expansion is a two-stage process. It first involves the use of a silicone rubber balloon-like tissue expander or implant that is inserted beneath the skin and chest muscle or over the muscle. Saline gradually is injected into the tissue expander to fill it over a period of weeks or months. This process allows the skin on the chest to be stretched over the expander, creating a breast mound. In most cases, once the skin has been stretched enough, the expander is surgically removed and replaced with a permanent breast implant

There are legitimate reasons to delay breast reconstruction. Some women may be advised by their surgeon or oncologist to wait until other forms of necessary cancer treatment are completed or disease staging has been accomplished. Other patients may require more complex breast reconstruction procedures. Women who smoke or who have other health conditions such as obesity may be advised to postpone surgery. Individuals with a weakened immune system (currently receiving chemotherapy or drugs to suppress the immune system), conditions that interfere with blood clotting or wound healing, or have reduced blood supply to the breast tissue from prior surgery or radiation therapy treatments may be at greater risk for complications and poor surgical outcome. In any case, being informed of your options concerning breast reconstruction can help you prepare for a mastectomy with a more positive outlook on the future.

The shape and size of your breasts prior to surgery will influence both the recommended placement of the tissue expander/implant and the final shape of your reconstructed breast. Tissue expander/implant breast reconstruction cannot produce an exact replica of the removed breast. Breast symmetry surgery on the opposite breast may be needed to produce similar size. The nipple and darker skin surrounding it, called the areola, may be reconstructed in a subsequent procedure after breast implants are placed as a third procedure.

As of May 2000, the United States Food and Drug Administration (USFDA) have approved saline-filled breast implant and tissue expander devices for use in breast reconstruction. Patients undergoing breast surgery with tissue expanders and implants must consider the following:

- Breast reconstruction with implants may not be a one-time surgery.
- Breast implants and tissue expanders of any type are not considered lifetime devices. They cannot be expected to last forever. You will likely require future surgery for implant replacement or removal.
- Changes that occur to the breasts following reconstruction with implants are not reversible. There may be an unacceptable appearance to the breast if you later choose to have breast implants or tissue expander removed.

Breast reconstruction with tissue expander/implant is an elective surgical operation. Alternative treatments would consist of the use of external breast prostheses or padding, breast reconstruction without tissue expansion, or the transfer of other body tissues for breast reconstruction. Potential risks and complications are associated with alternative surgical forms of treatment.

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Every surgical procedure involves a certain amount of risk, and it is important that you understand the risks involved with breast reconstruction with tissue expander/implant. 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. While the majority of women do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of breast reconstruction with tissue expander.

Problems associated with breast implants and tissue expanders can be inherent to this type of implanted medical device or relate to complications of a surgical procedure. Patients considering surgery that involves breast implants and tissue expanders should review additional advisory information regarding this subject. Additional information concerning breast implants and tissue expanders may be obtained from the FDA, package-insert sheets supplied by the device manufacturer, or other information pamphlets required by individual state laws.

While every patient experiences her own individual risks and benefits following tissue expander breast reconstruction, clinical data suggests that most women will be satisfied with the outcome of surgery despite the occurrence of problems inherent with breast implant and tissue expander surgery.

The most common risks associated with Breast Reconstruction with Tissue Expanders/Implant are as follows:

- 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 14 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. 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.
- 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, from no apparent cause (silent rupture), or during mammography. 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.

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Damaged, leaking, or broken tissue expanders and implants cannot be repaired and require replacement or removal. Breast implants and 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. Saline-filled breast implants may not have the same contour or feel as silicone-filled breast implants. The shape of your breasts after surgery depends on many factors such as your skin thickness, position, placement of the implants or expanders, and technique. You should discuss with your surgeon the possibility of a different and less than desirable contour-shape as well as feel of your result.

- **Pain**- You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after tissue expander surgery. Pain may occur during and after procedures to fill the tissue expander with saline fluid. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.
- **Capsular Contracture**- Scar tissue, which forms internally around the tissue expander, can tighten and make the breast round, firm, and possibly painful. Excessive firmness of the breasts can occur soon after surgery or years later. The occurrence of symptomatic capsular contracture is not predictable. 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. It is more common with tissue expander placement in front of the chest muscle layer. Treating capsular contracture may require surgery, tissue expander replacement, or tissue expander removal. **Capsular contracture may reoccur after surgical procedures to treat this condition.**
- **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.
- **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.
- **Change in Nipple and Skin Sensation**- Breast reconstruction cannot restore normal sensation to the breast or nipple after mastectomy. Changes in sensation may affect sexual response.
- **Skin Wrinkling and Rippling**- Visible and palpable wrinkling of implants or tissue expanders and breast skin can occur. Some wrinkling is normal and expected. This may be more pronounced in patients who have saline-filled implants with textured surfaces or thin tissue. It may be possible to feel the tissue expander fill valve. Some patients may find palpable valve and wrinkles cosmetically undesirable. Palpable valve, wrinkling and/or folds may be confused with palpable tumors and questionable cases must be investigated.
- **Calcification**- Calcium deposits can form in the scar tissue surrounding the tissue expander and may cause pain, firmness, and be visible on mammography. These deposits must be identified as different from calcium

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deposits that are a sign of breast cancer. Should this occur, additional surgery may be necessary to remove and examine calcifications.

- **Chest Wall Irregularities**- Chest wall irregularities have been reported secondary to the use of tissue expanders and breast implants. 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.
- **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.
- **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.
- **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.
- **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.
- **Thrombosed Veins**- Thrombosed veins, which resemble cords, occasionally develop in the area of the breast and resolve without medical or surgical treatment.
- **Skin Discoloration / Swelling**- Some bruising and swelling normally occurs after tissue expansion surgery. 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, "spitting" suture become visible or produce irritation that requires suture removal. If this happens you can dress the area with bacitracin and a dry gauze until you can get into the office.
- **Asymmetry**- Some breast asymmetry naturally occurs in most women. Differences in terms of breast and nipple shape, size, or symmetry may also occur after surgery. Additional surgery may be necessary to attempt improvement of asymmetry.
- **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.

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- **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.**
- **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.
- **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/expander 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 and not match the opposite breast. Unsatisfactory surgical scar location may occur. Tissue expander breast reconstruction may fail due to complications attributable to the mastectomy or from later chemotherapy/radiation therapy treatments. It may be necessary to perform additional surgery to improve your results, change size or remove and not replace tissue expander/breast implant.

ADDITIONAL ADVISORIES

Breast Disease- Current medical information does not demonstrate an increased risk of breast cancer in women who have tissue expander surgery. Individuals with a personal history or family history of breast cancer may be at a 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 seek professional care should they notice a breast lump. Care must be exercised during breast biopsy procedures to avoid damaging the tissue expander.

Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL): A type of lymphoma has been discovered around breast implants that is different than traditional female breast cancer. It typically presents as a late seroma (fluid around an implant greater than one year after surgery), breast mass, swollen lymph nodes, capsular contracture, or even as a rash. This has only been found in patients with a history of, or currently have, textured breast implants. At the time of this writing no patients with smooth implants only have been found, however it is not possible to exclude BIA-ALCL in smooth implants. As of August 2022, the US has 400 suspected/confirmed cases and 1,227 worldwide. Prognosis is very good when this is discovered early and when the fluid is the presenting finding. Treatment in most cases has been explanation with complete capsulectomy. Along with regular breast cancer surveillance patients with textured implants could consider routine ultrasounds and they should contact us immediately if they notice an increase in volume to a breast.

Breast Implant Associated squamous cell carcinoma (BIA-SCC): a very rare epithelial based tumor that appears to emanate from the breast implant capsule. It has been reported in patients with smooth and textured as well as silicone and saline implants. There have been 18 documented cases thus far (Aug. 2022). Current treatment is based on emerging data and presently appears to be removal of the implant with complete capsulectomy. Along with regular breast cancer surveillance patients with implants could consider routine ultrasounds and they should contact us immediately if they notice an increase in volume to a breast.

Radiation Therapy- Radiation therapy to the chest region before or after breast reconstruction with a tissue expander/breast implant can produce unacceptable firmness or other long-term complications.

Long-Term Results- Subsequent alterations in breast shape may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause, or other circumstances not related to your breast

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reconstruction.

Removal / Replacement of Tissue Expander- Tissue expander breast reconstruction is a two-step process. Removal of the tissue expander, revision of the surrounding scar tissue envelope, or replacement of tissue expander with a permanent breast implant involves surgical procedures with risks and potential complications. There may be an unacceptable appearance of the breasts following removal of the implant.

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

Breast Feeding- If a woman has undergone a mastectomy, she will not be able to breast feed a baby on the side where the breast was removed.

Breast and Nipple Piercing Procedures- Individuals with breast implants or tissue expanders 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.

Mental Health 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.

Breast Implant and Expander Technology / Technologic Improvements - The technology of breast implant and expander design, development and manufacture will continue to progress and improve. Newer or future generations of implants/expanders may be better in some way from those currently available.

Female Patient Information- It is important to inform your plastic surgeon if you use 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 that 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.

COVID-19 Infection: If you were to become symptomatic with a COVID-19 infection during your recovery, it could increase your morbidity/mortality and complication rate. There are still many unknowns, and

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recommendations about COVID-19 do change rapidly. Please follow the updated local health recommendations regarding COVID-19 to protect yourselves and others on: www.denvergov.org/Government/COVID-19-Information.

By signing this consent, I understand I am opting for an elective treatment/procedure/surgery that is not urgent and may not be medically necessary. I understand that possible exposure to COVID-19 before/during/after my treatment/procedure/surgery may result in: a positive COVID-19 diagnosis, extended quarantine/self-isolation, additional tests, emergency room visits or hospitalization that may require medical therapy, Intensive Care treatment, possible need for short or long-term intubation/ventilator support, risk of death, and possible additional risks which may not currently be known at this time.

Nerve graft: If indicated we utilize a cadaveric nerve allograft to provide additional sensation following a mastectomy. This Axogen graft is attached to one of the branches of the nerve that comes from the chest wall and then to the undersurface of the areola. Studies suggest that this nerve grafting may diminish chronic pain and discomfort associated with the mastectomy. Some patients will still have a risk of this despite our best efforts. Some patients will develop protective sensation such as hot and cold stimuli, and others will develop relatively full sensation. This process takes 12-18 months to complete. Factors such as chemotherapy and radiation therapy will likely affect nerve regrowth and final outcomes. There are also instances where this portion of the reconstruction is not possible. This could include tumors that are adjacent to these nerves – we cannot compromise the cancer component of the surgery to isolate these nerve branches. Other anatomical limitations include nerve branches that are prohibitively short or poorly located, or larger implants may preclude our ability to perform this component of the reconstruction.

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. Please indicate your current status regarding these items below:

_____ I am a non-smoker and do not use nicotine products. I understand the 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.

ADDITIONAL SURGERY NECESSARY

Many variable conditions may influence the long-term result of breast reconstruction surgery with tissue expanders/implants. It is unknown how your breast tissue may respond to implants/expanders or how wound healing will occur after surgery. Secondary surgery may be necessary at some unknown time to replace your tissue expanders/implants or to improve your outcome. You may elect to or be advised to have your breast implants/expander removed and not replaced in the future. Should complications occur, additional surgery or

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other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with breast reconstruction with tissue expander 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 activities must be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful post-operative results depend 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.

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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.

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 that 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 following consent.

Medicine is not an exact science, so no guarantees can be made regarding complications or outcome. We do everything possible to ensure your safety, and strive for the best result in every case. We hope that you will also do your part by following your post-operative instructions, using good judgment and letting us know if there are any problems.

Please ask any questions you may have regarding the surgery or potential risks prior to signing this form. Your signature means that you have had a chance to read and discuss the common risks associated with Breast Reconstruction with Tissue Expander surgery and that you agree to proceed. A separate consent form from the hospital will also need to be signed for the medical record.

I CONSENT TO THE TREATMENT OF BREAST RECONSTRUCTION WITH TISSUE EXPANDERS OR IMPLANTS AND I HAVE READ THE ABOVE LISTED ITEMS. I AM SATISFIED WITH THE INFORMED CONSENT PROCESS

Patient or Person Authorized to Sign for Patient

Date

Witness

Date