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CONSENT FOR SECOND STAGE BREAST RECONSTRUCTION SURGERY

Second Stage Breast Reconstruction is a surgical procedure performed to enlarge the breasts for a number of reasons:

- To restore breast shape after partial or total loss of the breast(s) for various conditions.
- To replace existing breast implants for reconstructive reasons.

Breast implant surgery is contraindicated in women with untreated breast cancer or pre-malignant breast disorders, active infection anywhere in the body, or individuals who are currently pregnant or nursing. 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 with reduced blood supply to the breast tissue from prior surgery or radiation therapy treatments may be at greater risk for complications and a poor surgical outcome. According to the USFDA, a woman should be at least 18 years of age for Second Stage Breast Reconstruction.

Breast reconstruction is accomplished by inserting a breast implant partially or completely under the chest muscles or completely above. Breast implants are manufactured in a variety of shapes, sizes, and with either smooth or textured surfaces. The method of implant selection and size, along with surgical approach for inserting and positioning breast implants, will depend on your preferences, your anatomy and your surgeon's recommendation.

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 afterward.

Conditions that involve sagging of the breast or diminished skin tone (stretch marks) may require additional surgical procedures (breast lift) to reposition the nipple and areola upward and to remove loose skin.

Patients undergoing Second Stage Breast Reconstruction surgery must consider the following:

- Second Stage Breast Reconstruction may not be a one-time surgery.
- Breast implants 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 are not reversible. There may be an unacceptable appearance to the breast if you later choose to have breast implants removed.

Alternative treatment would consist of not undergoing the surgical procedure or use of external breast prostheses or padding, or the transfer of other body tissues to enlarge/rebuild breast size. Risks and potential complications are also associated with alternative surgical forms of treatment.

Additional information concerning breast implants may be obtained from the FDA package-insert sheets supplied by the implant manufacturer, or other information pamphlets required by individual state laws.

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 complications, you should discuss each of them

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with your plastic surgeon to make sure you understand all possible consequences of Second Stage Breast Reconstruction.

We often describe patients as being “good” or “poor” candidates for a particular procedure. This decision is made after taking into consideration factors such as physical findings (e.g., skin quality, body weight, degree of deformity), medical health, history of smoking, emotional state, level of expectation, and whether, in our hands, we can achieve a result that will meet your expectations. If you are told you are not currently a good candidate for a particular procedure, be sure to find out what, if anything, can be done to change this.

Second Stage Breast Reconstruction is an elective surgery, which means that it is being performed by choice rather than out of medical necessity. Every surgical procedure has some degree of unavoidable risk. Problems associated with breast implants can be inherent to this type of implanted medical device or relate to complications of a surgical procedure. When considering elective surgery, the risks and benefits must be carefully weighed because the only way to avoid the risks entirely is by choosing not to have surgery. It is important that you understand these risks and the possible complications associated with them. In addition to risks, every procedure has limitations. This “Consent for Second Stage Breast Reconstruction Surgery” will explain the general risks of having surgery, as well as those specifically associated with **Second Stage Breast Reconstruction** and the use of implants.

The most common risks associated with Second Stage Breast Reconstruction surgery are as follows:

- **Bleeding:** Very little blood is lost at the time of surgery. 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 the accumulated blood. When a significant amount of blood collects at the surgical site it is called a “hematoma” and will likely need to be drained in the operating room. Hematoma can occur at any time following injury to the breast, and may contribute to capsular contracture, infection, or other problems. It is very important to stay off all blood thinning medications for two weeks before and after surgery. Do not take any aspirin or anti-inflammatory medications 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. Vitamin E, untested supplements, a variety of other prescription and over the counter medications should be avoided. At your pre-op appointment you will be given a lengthy list of medications to avoid. After surgery, the risk of bleeding can be reduced significantly by not straining or exerting yourself for at least four weeks, and by keeping your arms at your sides as much as possible for that same period. Small amounts of bleeding can be absorbed by the body but can still impact healing.
- **Infection:** Bacteria live on the skin and within the ducts of the breast. You will be given antibiotics through your I.V. at the time of surgery. 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 breast implant. Subacute 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. The biggest problem in trying to treat an infection is that the body cannot re-sterilize the implant if an infection is present the implant must be removed. Replacement of the implant should not occur before three months from the time of explanation.

Individuals with an active infection in their body or weakened immune system should not undergo Second Stage Breast Reconstruction. The reported infection rate following Second Stage Breast Reconstruction is about 2%. In extremely rare instances, life-threatening infections, including toxic shock syndrome have been noted after breast implant surgery.

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- **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.
- **Asymmetry:** It is unusual to find a person with perfectly symmetric breasts. Because the body is not completely symmetric and most people have a dominant upper extremity, there is usually a small amount of asymmetry following this type of surgery. Differences in terms of breast and nipple shape, size, or symmetry may also occur after surgery. These small degrees of asymmetry need to be accepted. Large degrees of asymmetry may be improved with additional surgery.
- **Capsular Contracture:** Your body knows that a large piece of foreign material, such as an implant, doesn't belong there. During the course of healing, everyone will develop a layer of scar tissue, which is called a "capsule," internally around the implant. This capsule may tighten immediately or over time, causing hardening of the breast, distortion, and even pain. The occurrence of symptoms related to capsular contracture is not predictable. Capsular contracture may occur on one side, both sides or not at all. Published rates for capsular contractures are about 5% at one year and 10% over three years following augmentation. The incidence of symptomatic capsular contracture can be expected to increase over time. For patients having reconstruction, the rates are closer to 30%.

In general, implants make the breasts much firmer, which you may like or dislike, depending on your individual preference. A very mild contracture (where one breast is slightly firmer than the other) is common. Because this does not cause pain or significant degree of breast distortion, it can be treated with massage. More severe contractures require a surgical procedure to remove the scar tissue from around the implant with removal and/or replacement of the implants. Unfortunately, there is no guarantee that the capsular contracture will not recur, as it may be your body's natural reaction to having an implant.

Implants placed below the muscle have a lower rate of capsular contracture. We believe that post-operative infection and bleeding can increase your risk of capsular contracture. Additional measures to prevent contracture include massage of the implants. Although there is no documented proof, we also recommend using antibiotic prophylaxis for one year after surgery when having dental work or undergoing a procedure that spreads bacteria in the blood stream.

Over time, small amounts of silicone gel material can pass through the shell layer of the implant and coat the outside of the implant. This may contribute to capsular contracture.

- **Calcification:** Calcium deposits can form in the scar tissue surrounding the implant and may cause pain, firmness, and be visible on mammography. These deposits must be identified as different from calcium deposits that are a sign of breast cancer. Should this occur, additional surgery may be necessary to remove and examine calcifications.
- **Pain:** Expect discomfort for around the first month, but things should improve over time. Severe pain is not expected, and you should be examined if there is a problem. Implants that are too large for your frame, nerve entrapment, and severe capsular contractures can result in chronic pain.
- **Change in Nipple and Skin Sensation:** Nerves that provide sensation to the nipple come from branches through the ribs and around the lateral (side) of the breast. After mastectomy most people will experience a decrease in nipple sensation following this type of surgery.
- **Problems with Mammograms:** After bilateral mastectomy you will not need to have routine mammograms. If you retained a natural breast on one side, you would still need regular mammogram imaging. There has never been any evidence that having implants increases your chance of developing breast cancer, but the presence of an implant can make mammography more difficult. Future mammograms can require special views, so be sure to inform the technician performing the study that you have implants. 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.

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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. Care must be exercised during breast biopsy procedures to avoid damaging the breast implant.

- **Inability to Breast Feed:** If you have one natural breast with an augmentation for symmetry there have not been many studies on breast feeding after implants, but one study did show that 64% of patients were *unable* to breast feed following augmentation compared to 7% who had not had surgery. It is felt that the incisions around the nipple create a higher risk. There are also concerns that silicone can be transmitted through the breast milk when breast feeding and very little is known about the possible affects this could have. A study measuring elemental silicon (a component of silicone) in human breast milk did not indicate higher levels from women with silicone-filled gel implants when compared to women without implants.
- **Problems with 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. There could be problems with healing due to infection, seroma (fluid collection), or tissue breakdown (necrosis) at the surgical site. Lack of adequate tissue coverage or infection may result in exposure and extrusion of the implant through the skin. Risk factors for tissue breakdown or necrosis include a depressed immune system, steroid use, smoking, history of radiation, and exposure to extreme temperatures. If tissue around the implant does not heal and the implant becomes exposed to the outside world, it will need to be removed. In some cases, incision sites fail to heal normally. Permanent scar deformity may occur. **Smokers have a greater risk of skin loss and wound healing complications.**
- **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.
- **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.
- **Poor Appearing Scars:** The incisions used for this surgery vary depending on treatment plan and location of cancer. 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 are many things that you can do after surgery to improve the appearance of the scars. It will take one year before you know how the scars will ultimately heal. Surgery for scar revision is rarely needed.
- **Palpable Implants or Visible Skin Wrinkles/Ripples:** You will examine and hold the various available implants at your consultation and pre-op appointment. When touching the implants, it is obvious that saline implants will be more palpable (evident to touch) than the silicone, and that textured implants will have more ripples than smooth-walled implants. Visible and palpable wrinkling of implants and breast skin can occur post-operatively. Some wrinkling is normal and expected with breast implants. The less soft tissue present over the implant (i.e. smaller breasts, thinner patients, and implants placed above the muscle), the more palpable the implant will be. Also, the larger the implant, the more you will be able to feel it. Under-filling saline implants leaves them slightly softer but with more palpable ripples. Palpable wrinkling and/or folds may be confused with palpable tumors and questionable cases must be investigated.
- **Implant Rupture or Deflation:** Breast implants, like other medical devices, can fail. Implants are not intended to last a lifetime. They are exposed to forces daily that can create wear and tear, and at some point, may actually rupture. Rupture can occur as a result of an injury, from no apparent cause (silent rupture), or

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during mammography. It is also possible to damage an implant at the time of surgery. Damaged or broken implants cannot be repaired. Ruptured or damaged implants require replacement or removal.

If a saline implant ruptures (due to fatigue of the shell, valve malfunction, or trauma) it will deflate over the course of days. Once the implant ruptures the capsule may start to get smaller, so unless the replacement is done immediately, more extensive surgery will be required to remove the scar tissue (“capsulotomy”) when the new implant is placed.

When a silicone gel-filled implant ruptures, the gel material is usually contained within the scar tissue surrounding the implant (intracapsular rupture). In some cases, the gel may escape beyond the capsule layer and go into the breast tissue itself (extracapsular rupture and gel migration). Silicone implant rupture may not be obvious to the patient or physician. A change in breast shape or new capsular contracture might raise suspicion, but this is not always reliable. Mammography is not very good at identifying a rupture, but ultrasound and MRI are more sensitive. MRI studies may be necessary to evaluate the possibility of implant rupture, yet it may not be 100% accurate in diagnosing implant integrity

A ruptured silicone gel implant is not an emergency, but over time the gel may travel into the breast tissue and cause a palpable mass. Since we all associate lumps with the possibility of breast cancer, it can be alarming. The new silicone gel implants are much stronger than those manufactured in the 80’s, and we are still collecting data as to their rupture rates over the long term. Implant companies recommend MRI’s or Ultrasound at 3 years post-op and every 2 years after that. It is reasonable to consider replacing your implants every 10-15 years.

- **Implant Malposition or Displacement and Tissue Stretching:** Displacement, rotation, or migration of a breast implant may occur from its initial placement and can be accompanied by discomfort and/or distortion in breast shape (visible rippling of the skin). Unfortunately, most breasts are not symmetric. Placement of the implant takes into consideration the shape of the breasts/chest wall, laxity of skin, and size of the implants.

Over time the implant positioning can change due to the weight of the implant, stretching of the skin, and massage. The type of bra worn post-operatively can also influence the positioning of the implant (i.e., sports bras and push-up bras can force the implants too close together; no bra, or those with poor support can allow them to drop too low).

The ultimate positioning of the implants can end up slightly too high or low, too close together or far apart, and the breasts may still have some degree of ptosis. Heavier implants will also continue to stretch the skin over time, just like naturally large breasts. Additional surgery may be necessary to attempt to correct this problem. It may not be possible to resolve this problem once it has occurred.

Dissatisfaction with Cosmetic Results: The sizes recommended for your surgery are decided according to chest shape, the size of your rib cage, laxity of your skin, your body shape, and finally, your goal cup size. In the setting of reconstruction sometimes location of the tumor, previous treatments and planned following treatments limit choices. Implants that are either too large or too small based on the overall picture can result in a poor cosmetic result. To create the most natural breast shape and good long-term result, you may end up being either larger or smaller than your personal ideal. Be sure to communicate your personal goals as clearly as possible and listen closely if you are warned that these goals may not be possible with your features.

- **Deformity if the Implant is Removed:** At some point you may want to have your implants removed. The implants cause pressure in the chest wall and the skin over time, and there may be some atrophy resulting in smaller or droopier skin once the implants are removed.
- **Risks of Surgery and Anesthesia:** There are additional risks associated with having surgery, including medication reactions, and complications from 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. Other risks include pneumonia, deep venous thrombosis (blood clot in the leg), and pulmonary

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embolus (clot that travels to the lung), and 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 anaphylaxis may occur in response to drugs used during surgery and prescription medicines. These are rare but are possible with any type of surgery.

- **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 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 shortness of breath, chest pains, or unusual heart beats after surgery, seek medical attention immediately.
- **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.
- **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.
- **Photographs:** Pre-operative and post-operative photos will be taken to help with surgical planning and to document results. Your photos (which never include your face) may also be used for teaching purposes to help doctors or other patients but only if you have signed a consent to do so.
- **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 reconstruction.

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ADDITIONAL ADVISORIES:

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 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.

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 issues. 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 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 can be 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.

Additional Surgery Necessary (Re-operations)

There are many variable conditions that may influence the long-term result of Second Stage Breast Reconstruction 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 Second Stage Breast Reconstruction 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 Second Stage Breast Reconstruction surgery. Other complications and risks can occur but are even more uncommon. Although good results are expected, there is no guarantee on the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure.

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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 if present 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.

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 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 based on 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 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 Second Stage Breast Reconstruction 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 SECOND STAGE BREAST RECONSTRUCTION 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