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CONSENT FOR BREAST IMPLANT REMOVAL

GENERAL INFORMATION

The removal of breast implants that have been placed either for cosmetic or reconstructive purposes is a surgical operation. Breast implant removal may be performed as a single surgical procedure or combined with additional procedures, for example:

- Simple breast implant removal, without removal of capsule tissue around implant
- Removal of tissue surrounding the breast implant (capsulectomy)
- Removal of escaped silicone gel in breast tissue (extra capsular, outside of capsule layer) from silicone gel-filled implants (breast biopsy)
- Breast lift (mastopexy following breast implant and/or capsule removal)

Implants that are found to be damaged or ruptured cannot be repaired; surgical removal or replacement is recommended. There are options concerning general versus local anesthesia for breast implant removal.

Alternative treatment would consist of not undergoing breast-implant removal, or other procedures to replace, relocate, or revise existing situations where patients choose to continue with breast implants. Risks and potential complications are associated with alternative surgical forms of treatment.

An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of women do not experience 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 implant removal.

The most common risks associated with Breast Implant Removal 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. Individuals undergoing removal of capsule tissue or breast biopsy to remove escaped silicone gel (if applicable) are at a greater risk of bleeding than simple breast implant removal 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 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. Subacute or chronic infections may be difficult to diagnose. Should an infection occur, treatment including antibiotics, or additional surgery may be necessary.
- **Firmness:** Excessive firmness of the breasts can occur after surgery due to internal scarring. The occurrence of this is not predictable. Additional treatment including surgery may be necessary.

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- **Seroma:** Fluid may accumulate in the surgical area following surgery, trauma or vigorous exercise. Additional treatment may be necessary to drain fluid accumulation. This may contribute to infection, 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.
- **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.
- **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. When the pocket for your implant was created, these nerves were stretched, and sometimes even cut. Most people will experience a decrease in nipple sensation following this type of surgery, although some become hypersensitive. Approximately 15% will lose sensation and it may take a year before maximal return is seen. In some cases, nipple numbness can be permanent.
- **Problems with Mammograms:** Unfortunately, all women are at risk for developing breast cancer. 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. We *require* that all women over the age of 40, or 35 with a family history of breast cancer have a baseline mammogram prior to any breast surgery. Some people deposit calcium in their scar capsule, which could show up on a mammogram, it is possible to have the capsule left behind when removing the implants. 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.
- **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. Risk factors for tissue breakdown or necrosis include a depressed immune system, steroid use, smoking, history of radiation, and exposure to extreme temperatures. 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 are fairly short (1-2 inches) and are located on the undersurface of the breast or at the edge of the areola. 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.
- **Skin Wrinkling and Rippling-** Visible and palpable wrinkling of breast skin can occur. This may require additional surgery to tighten loose skin following breast implant removal surgery.

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- **Ruptured Silicone Gel-Filled Breast Implants-** As with any man-made object implanted in the human body, device failure can occur. It is possible that an implant can rupture causing silicone gel to be released from the implant. Implants also can rupture during the removal process. If implant rupture has occurred, it may not be possible to completely remove all of the silicone gel that has escaped. Implant shell material of textured breast implants may be impossible to completely remove. Calcification around implants can occur and may require removal of the scar tissue surrounding the implant (capsulectomy). It may not be possible to completely remove the scar tissue that has formed around a breast implant, implant parts, calcifications, or silicone gel. Additional surgery may be necessary in the future.
- **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.
- **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 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 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 shortness of breath, chest pains, or unusual heart beats after surgery, seek medical attention immediately.
- **Skin Contour Irregularities-** Contour and shape irregularities may occur. Visible and palpable wrinkling may occur. One breast may be smaller than the other. Nipple position and shape will not be identical one side to the next. 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.
- **Psychological / Appearance Changes-** It is possible that after breast implant removal you may experience a strong negative effect on your physical appearance, including significant loss of breast volume, distortion, and wrinkling of the skin. Your appearance may be worse than prior to your surgery for the placement of the breast implants. There is the possibility of severe psychological disturbances including depression. It is possible that you or your partner will lose interest in sexual relations.
- **Health Disorders Alleged To Be Caused By Breast Implants-** Currently there is insufficient evidence to state that the removal of breast implant(s) and capsule(s) will alter the course or prevent autoimmune or other disorders alleged to be caused by breast implants. **The removal of breast implants may be of no health benefit to you.**
- **Breast Disease-** Current medical information does not demonstrate an increased risk of breast disease or breast cancer in women who have breast implant surgery for either cosmetic or reconstructive purposes. Breast disease can occur independently of breast implants and surgical procedures to remove them. 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-examinations of their breasts, have mammography per American Cancer Society guidelines, and

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seek professional care should they notice a breast lump.

- Breast Feeding Following Implant Removal-** It is not known if there are increased risks in nursing for a woman who has undergone breast implant removal
- Dissatisfaction with Cosmetic Results:** Some patients come in with photographs of models, or expectations that their breasts can look “perfect” after this surgery. They may also request an exact bra size. While using photographs of other people helps show what you like and dislike, it doesn’t ensure that you can be made to look like someone else. The sizes recommended for your surgery are decided according to how much breast tissue you have, the size of your rib cage, laxity of your skin, your body shape In order to create the most natural breast shape and good long-term result, you may end up being smaller than your personal ideal and may need a mastopexy (to tighten loose skin) or a fat transfer to help create some of the lost volume. 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.
- 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 with your consent.
- 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 breast implant removal. Breast sagginess after the procedure will normally occur.

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

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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 breast implant removal surgery. It is unknown how your breast tissue may respond 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. 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 implant removal 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.

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 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 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 implant removal surgery, and that you agree to proceed. A separate consent form from the hospital will also need to be signed for the medical record.

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I CONSENT TO THE TREATMENT OF BREAST IMPLANT REMOVAL 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