BREAST IMPLANT SURGERY CONSENT

PATIENT:       DATE:

Permission includes the administration of medicines for local or general anesthesia and/or intravenous sedation or analgesia as deemed suitable or as become necessary. An informed consent requires that common complications be made known to you. Most of these are not expected to occur. All must be considered. The law requires that you be made informed.

1. **MEDICATION:** Unfavorable reaction to prescribed medications or anesthesia can occur. This may include nausea vomiting, allergic reactions with skin rash and itching to more severe reactions including convulsions, coma or death.

2. **EDEMA** (Swelling): This occurs to some degree after every surgery. It may last days, weeks or months. Some swelling may remain after surgery for a year or more. You will be given special instructions or treatment if appropriate.

3. **BLEEDING:** This is controlled at the time of surgery by sutures, cautery, or pressure. Hematoma (blood clot) may require removal. Some bloody drainage on dressings is normal. If bleeding occurs, phone our office. If we cannot be reached promptly, and there are problems that are of concern, go to the nearest hospital emergency room. In a very rare case, extensive bleeding or other complications could require hospitalization and blood transfusion. With most surgery, there is bleeding or other complications that could require hospitalization and blood transfusion. With most surgery there is bleeding under the skin that leaves a bluish discoloration (bruising) for two or more weeks.

4. **INFECTION:** This may require implant removal and replacement with a new implant at a later time. Infection may occur with any break in the skin or with any operation, or following pregnancy. When infection occurs around a breast implant, then the implant will probably have to be removed. It may occur on only one side. When the implant is removed it is necessary to leave it out for a period of months to be sure that the tissues are completely free of infection before it is replaced. It is sometimes necessary to wait six months or more before replacing the implant.

5. **SCARRING:** Some scar will result wherever there is a cut. We make every effort to place scars in areas where they will be minimal or invisible. Healing tendency to scar is very variable in different persons and in different areas of the body of the same person. How well a person will heal cannot be exactly predicted or controlled. Extensive wide or thickened scars (hypertrophic or keloid) may occur if you are prone to them.

*I have been informed of the common complications listed on this page _____ (initial)*
6. **NUMBNESS**: In cutting the skin, small nerve endings are also cut that can result in numbness around or adjacent to the surgical area. Sensation usually returns in a matter of months or years as the small nerve endings regrow. Rarely is an area permanently numb. Most numbness or weakness fades away in time.

7. **RESPIRATION AND HEART FAILURE**: These are unusual complications of anesthesia. They are, however, known risks. Heart attacks or stroke may occur.

8. **PNEUMOTHORAX AND SEROMA**: Pneumothorax (life threatening lung collapse due to air in the chest and tissues around but outside the lungs) may occur and may require hospitalization, chest tubes and additional incisions and treatment. Seroma is a fluid collection of serum around one or both implants as a reaction to the implant or infection. This may require treatment, medicines, drainage and could require removal of one or both implants as described.

9. **PHOTOGRAPHS**: I consent to be photographed before, during and after the treatment. I agree that these photographs become the property of the doctor, to be used, as he deems proper. I consent to the publication of these photographs in any medical journal, article, magazine or book. My permission is granted to show these photographs to any other physicians, patients or persons, although in a confidential manner.

10. **FOLLOW UP CARE AND APPOINTMENTS**: I agree to keep the doctor informed of any change of address and phone numbers, and I agree to cooperate with the doctor in my care after the surgery until completely discharged. I will make and keep follow up appointments, take medications, and follow other instructions as prescribed.

11. **POSTOPERATIVE DEPRESSION**: Is common after any form of cosmetic surgery. Such depression is usually related to the immediate postoperative discomfort, drugs, anxiety over a distorted appearance (swelling and bruising), and limitation of activities and socializing. As you appearance improves and you return to your usual activities and interests, these feelings should disappear.

12. **MEDICAL HISTORY**: I have given a complete history of previous surgery and hospitalizations and all previous physical and mental illnesses in writing on a separate form, including all medications or drugs that have been taken or to which I am allergic.

13. **ADDITIONAL PROCEDURES**: I authorize the surgeon to perform any other procedures, which he may deem necessary, or desirable to correct any unforeseen condition encountered during surgery for the purpose indicated above.

14. **SYMMETRY**: It is understood that the two sides of our bodies are different and asymmetrical and this includes the chest, breast, nipples and all other parts of our faces and bodies. While we usually want to make our two sides more alike, it is understood that it is not possible to make them alike. The two sides of our bodies and every part of our breasts will always be different, unequal and asymmetrical in every way to some degree.

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15. **REVISIONS:** When we have cosmetic surgery we want an improvement in appearance and want to look as good as possible. Even after the surgery is done, most of us still want to look better. This may be true when the surgery has been very successful. Sometimes because the appearance is improved with so little discomfort the patient wants more. Many patients want to look better than is possible. The expectations may be greater than the doctor can achieve. The results of surgery are never perfect. The results can never match a preconceived drawing, picture or goal. If further surgery is desired to look better, even in the previously operated area, there will be additional charges. Though the patient may want more improvement, the surgeon may believe the risks outweigh the rewards to the patient. It is understood there will be some additional charges for revision surgery or repair work done.

16. **SAGGING OF THE BREAST:** While women with breast implants may sag no more than those of the same size without, the implants do have some weight and can cause some additional sagging of the breasts as can pregnancy, weight gain, and aging.

17. **WRINKLING AND RIPPLING:** The textured implants have a thicker wall than the smooth implants. They are made textured to stay softer and not allow capsule contracture. The thicker wall that is required for the textured surface can cause wrinkling or rippling that can be seen after surgery through the skin. If the breast tissue is very thin these wrinkles can show as visible ripples, especially when you lean forward without wearing a bra. This rippling can and often occurs with any implant and the degree of rippling CANNOT be predicted.

18. **CAPSULE CONTRACTURE:** The most common problem with any type of breast implant is firmness due to capsule contracture. The incidence varies with the type of implants. Hardness and deformity in appearance often follow pregnancy. Contracture is also more common with silicone-gel than saline implants. Some women can’t tolerate implants without having undesirable capsule contracture.

19. **INSION SITE, LOCATION, SIZE, SHAPE AND IMPLANT SIZE, SHAPE, POSITION, LOCATION AND TYPE:** Though these factors may be discussed and the patient’s wishes may be followed as much as prudent and reasonable, the patient must agree to whatever treatment or surgery necessary, advisable or available at the time of and during the operation. Permission granted for other incisions, implants or treatments may be as needed. No certain preconceived appearance or result can be obtained. Other incision sites may be needed later if there are problems.

20. **REJECTION OR EXTRUSION:** The body may recognize the implant as a foreign object and try to reject it. The capsule contracture problem of becoming too hard may be part of the rejection phenomenon. Occasionally the implant may be pushed from the inside by the rejection process against the skin causing it to become very thin and a “blue window” may occur. The implant may be pushed against the skin until the skin over the implant breaks and the implant becomes exposed. When this occurs the implant extrudes or is removed.

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21. **IMPLANT RUPTURE**: Implants may rupture at any time following surgery even without apparent cause. The most common cause of rupture is injury. A ruptured gel implant may result in gel migration, inflammation, and formation of silicone granulomas. Additional surgery may be required to remove the implant and the gel. The long-term effect of silicone gel on the body with a ruptured implant is unknown.

22. **DISPLACEMENT AND DISTORTION**: Implants may become displaced, or distortion in breast shape and appearance may occur. This is usually a part of the capsule contracture phenomenon. The implants may seem to be too high or too low, too far to the side or in any other conceivable abnormal; unequal position. The tissues and skin over the sternum or breastbone may eventually lift forward causing an apparent communication from one side to the other. This may require further surgery. Not all problems can be corrected. Many problems in appearance cannot be corrected or improved.

23. **SKIN NECROSIS**: Skin over a portion of the implant may become very thin and break. The implants may become exposed and require removal. Then it may be best to wait six months for replacement with a new implant.

24. **GEL BLEED**: All implants filled with silicone gel may leak or bleed through the shell even when the implant is not ruptures. The long-term effects of a gel bleed are unknown. Over many years gel bleed could be harmful.

25. **LEAKING IMPLANTS AND DEFLATION**: Saline filled implants are expected to leak and eventually collapse. The saline is not harmful to the body. If the leakage and deflation are only on one side then this may cause distortion in appearance. It is estimated that noticeable loss of saline will occur in as many as 50% or more persons who have saline implants for seven or more years. Further surgery is required to replace the implants at additional cost.

26. **CHANGE IN NIPPLE SENSATION**: Some numbness is expected with each operation. The numbness is most often in the lower portion of the skin below the nipple. Occasionally there is some numbness of the nipples from breast surgery. Most of the numbness goes way in a period of months or years. Some numbness may be permanent and unequal. There also may be hypersensitivity.

27. **INTERFERENCE WITH MAMMOGRAPHY**: The presence of breast implants of any type can interfere with mammography and may delay early detection of breast cancer. Mammograms may be more uncomfortable since they require squeezing the breast with pressure. The pressure of mammography may rupture an implant or cause implant deflation with saline implants. The standard recommendation of the American Cancer Society should be followed for when to have mammography. ACS recommends that at the age of 40 a base line mammogram should be done. Between 40-50 mammograms should be done once every two years. Women over age 50 should have a mammogram every year. Mammograms should be done more frequently when there is a family history of breast cancer.

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28. **AUTOIMMUNE DISEASE:** Some women with breast implants have developed scleroderma, which is a serious disabling and potentially fatal connective tissue disease. Some women have developed arthritis like diseases such as lupus and rheumatoid arthritis after breast implant surgery. According to the Food & Drug Administration, “There is no conclusive evidence at present that women with breast implants have an increased risk of developing arthritis like diseases or other autoimmune diseases. Women with breast implants who have developed such diseases may have done so regardless of their implants.”

29. **BREASTFEEDING:** Many patients have become pregnant and have breast fed infants after breast implant surgery. Breast implants may interfere with breastfeeding in many different ways. There may be numbness or hypersensitivity of the nipples. There may be tenderness or inadequate milk production. Pregnancy after breast implant surgery may cause stretching of the skin and deformity of the shape of the breast or stretch marks of the skin. There is an increase in capsular contracture following pregnancy and breastfeeding.

30. **AXILLARY INCISION:** There may be numbness or pain of the arms around the incision or of the upper part of the arms, forearms or hands. These problems are uncommon but could occur even when the surgery is perfectly performed. Another incision site may be necessary if there are any problems at this surgery or a later surgery.

31. **BREAST CANCER AND IMPLANTS:** Breast implants may interfere with early detection of breast cancer. This could mean women with breast implants have a reduced cure rate with breast cancer. Approximately 3 million American women have breast implants. Women with breast implants have not been shown to have an increased risk of breast cancer, and according to the FDA “there is no evidence at present that women with breast cancer are at increased risk.” Studies are still in progress and the results may not be known for years.

32. **RISK TO UNBORN BABIES:** Possibilities of risk to unborn babies cannot be ruled out. According to the FDA “there is no evidence at present that women with breast implants or their unborn babies are at increased risk.”

33. **SYMMETRY AND ASYMMETRY:** No two breasts are alike and in some women they are very different. Breast implant surgery may make the unequal appearance of the breast better or worse. The breast cannot be made equal or alike.

34. **DEFORMITIES OF APPEARANCE:** Many deformities and disfigurements of appearance can occur after breast implant surgery. Among these are a stuck on appearance, nipples pointing down, the ball in the sock appearance, the double bubble deformity, the unibreast, unequal size, shape and direction of pointing nipples, sagging as well as too much or too little cleavage and many others.

35. **STRECH MARKS OR STRIAE:** Stretch marks, such as of the skin of the abdomen following pregnancy may occur in breasts. They may not occur until after pregnancy of many months or years later. Birth control pills seem to cause them in some persons. They may occur in women after implants for no explained reason.

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36. **MUSCLE MOVEMENT:** Implants that are placed below the pectoral muscle may move whenever the muscle is contracted in normal movements of the arms. This may also cause visible distortion of the appearance of the breasts with movement of the arms. Occasionally the movement is so annoying the woman has further surgery to put the implants above the muscle because of this problem.

37. **MUSCLE WEAKNESS:** Whenever the implants are places below the muscle, there is some weakness of the muscle because of the injury to the muscle itself or the nerve and blood supply to the muscle. The muscle is partly detached from the ribs and is otherwise injured by the surgery.

38. **DOUBLE FOLD OR BUBBLE:** A fold in addition to the new inframammary fold may occur in the lower part of the breast. This is due to a persistence of the normal inframammary fold or crease. It can cause a double bubble appearance, which may or may not improve in time.

39. **IMPLANT DURATION:** Implants may last years in some women and have to be replaced more frequently in others. The person choosing breast implants should expect to require further surgery to repair the implants in the future, especially if they are saline filled.

40. **UNKNOWN RISKS:** Although there are many risks that are known that can be described, there may be some risks that are still unknown.

41. **LONG TERM RISKS:** According to the FDA "The two greatest concerns most to most women with implants are cancer and autoimmune disease. But at this time there is no proven association with breast implants and the development of these diseases."

42. **ADDITIONAL COST:** Many of the problems known and unknown that can occur and may be related to breast implants may cause need of additional treatment or surgery. They may also cause prolonged illness, disability, hospitalization, diseases, deformity, disfigurement and death. Any and all of these may require additional expenses and costs to the person having breast implant surgery or her family.

43. **ABNORMAL APPEARANCE OR FEEL:** Implants are usually detectable. They may look or feel firmer. They may not move or jiggle the same as normal. The implants may be palpable. The valve may be palpable and the implant can often be felt through the skin. They may look “stuck on”, too high, too low, or unequal.

44. **SATISFACTION:** Cosmetic surgery is inexact and can be complicated. To achieve an improvement in appearance we undergo serious risks of discomfort and there is **NO GUARANTEE** that after either **YOU OR ANYONE ELSE WILL BE SATISFIED OR PLEASED WITH THE RESULT.**

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45. **NO GUARANTEE:** I am aware that the practice of medicine and surgery is not an exact science, and I acknowledge that no guarantees have been made to me as to the results of the operation or procedure. **IT IS UNDERSTOOD THAT MY RESULT CANNOT BE LIKE ANY PICTURE OR DRAWINGS OR ANY PRECONCEIVED IDEA OR GOAL.**

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Our patients are offered a copy of any form they sign.

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