

# Informed Consent For Breast Enlargement With Implants

I, \_\_\_\_\_ hereby authorize, Dr. Richard Fisher and associates or assistants of his choosing to enlarge my breasts by means of saline filled or silicone gel implants. **No guarantees** or assurances have been given to me by anyone as to the results that may be obtained. 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.

## *Nature of Breast Enlargement with Saline or Silicone Implants*

*Breast enlargement with implants is a surgical procedure whereby a polymer device filled with saline (salt water) or silicone gel is placed under the breasts through a surgical incision, either under the breast tissue itself above the chest muscle, or under the gland and under the covering of the chest muscle (subfascial), or under the gland and muscle chest. The result of the placement of this implant is to enlarge the size of the breasts.*

## ***Risks of Breast Enlargement with Saline or Silicone Gel Implants***

### ***Additional Surgery (Surgeries) Are Inevitable***

*I understand that breast implants are not permanent devices and that at some time subsequent to the original procedure an additional surgery or surgeries will be necessary for one or more of the reasons outlined in the risks of breast enlargement below.*

1. **MEDICATION REACTIONS:** 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 all of which are extremely rare.

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2. **SWELLING:** This occurs to some degree after every surgery. Swelling may last days, weeks or months. Some swelling may remain for a year or more after surgery although this is very unusual. You will be given special instructions or treatment if appropriate.

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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, and tell our answering service where you are going. In a very rare case, extensive bleeding or other complications 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.

Patient Initials \_\_\_\_\_

4. INFECTION: As with any surgery, particularly those that involve the implantation of foreign bodies into the body, infection can occur anytime after surgery from days, to months, to even years later. Infection of the breast tissue in the presence of saline or silicone gel implants almost always requires removal of the offending implant. The infection is then treated with the implant left out for a minimum of *three* months. When the infection has subsided a new implant can be placed. Infection of an implant therefore requires two additional surgeries, for which costs may be incurred. In most studies infections occur in about 1% of all implants. It is sometimes necessary to wait six months or more before replacing the implant.

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5. SCARS: Breast implants must be introduced into the breast through incisions. These incisions can be in the armpit, through the nipple, under the breast, or through the navel. All incisions leave scars that are permanent. Some scars can darken (hyperpigment), lighten (hypopigment), thicken or raise (hypertrophy). These complications of scar healing can be unsightly and may require further treatment and/or be permanent.

Patient Initials \_\_\_\_\_

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 re-grow. Rarely is an area permanently numb. Most numbness goes away in time.

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7. RESPIRATORY AND HEART FAILURE, BLOOD CLOTS TO THE LUNGS (PULMONARY EMBOLUS): These are unusual complications of anesthesia and surgery. They are, however, known risks. Heart attack or stroke may also occur.

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8. PNEUMOTHORAX AND SEROMA: Pneumothorax (life threatening lung collapse due to air in the chest and tissues around but outside of 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. This may require treatment, medicines, and drainage and could require removal of one or both implants as described for infection.

Patient Initials \_\_\_\_\_

9. DISSATISFACTION WITH THE SIZE OF THE IMPLANTS: The commonest cause of reoperation for breast enlargement with implants is patient dissatisfaction with the size of her breasts following surgery. As much as possible we involve you, the patient, in the selection of the implants to be used so as to give you the size you want. However, there are limitations to what can be safely performed and **no guarantee** can be given that we can achieve the size you have requested. Should you be dissatisfied with the size of your breasts after surgery and a reasonable time for them to heal (at least six months), and request re operation for different size of implant, you understand there will be additional charges incurred for this procedure.

Patient Initials \_\_\_\_\_

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

Patient Initials \_\_\_\_\_

11. POSTOPERATIVE DEPRESSION is not uncommon after any form of cosmetic surgery. Such depression is usually related to the immediate postoperative discomfort, anxiety over a distorted appearance (swelling and bruising) and limitation of activities and socializing. As your appearance improves and you return to your usual activities and interests these feelings should disappear.

Patient Initials \_\_\_\_\_

12. MEDICAL HISTORY: I have given a complete history of previous surgery and hospitalizations and all previous physical and mental illnesses to Dr. Fisher, including all medications or drugs that have been taken, are being taken or to which I am allergic.

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

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14. HOSPITAL ADMISSION: I understand that treatment of any unusual or serious complications requiring admission to a hospital is not covered by way of cost or charges quoted in connection with this surgery. In addition, I have been made aware that such complications could require the service of additional physicians and none of these fees or charges is included.

Patient Initials \_\_\_\_\_

15. SYMMETRY: It is understood that the two sides of our bodies are different and asymmetrical and this includes the chest, breasts, 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 exactly alike.

Patient Initials \_\_\_\_\_

16. REVISIONS: Revisions of breast implant surgery may be necessary or desirable whether it is due to an unsatisfactory result or a satisfactory result that does not meet the patient's expectations. The results of surgery are never perfect and care must be taken not to expect perfection. Revision surgery may incur additional costs.

Patient Initials \_\_\_\_\_

17. 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 subsequent pregnancy, weight gain, weight loss and aging.

Patient Initials \_\_\_\_\_

18. WRINKLING OR RIPPLING: If the breast tissue is very thin visible ripples, especially when leaning forward without wearing a brassiere can appear. These can be unsightly. Implants that are smooth, filled properly and placed under the muscle or fascia have greatly reduced rippling in thin women. In some patients rippling is unavoidable.

Patient Initials \_\_\_\_\_

19. CAPSULE CONTRACTURE: Implants are foreign bodies and as such, the body responds by forming a fibrous shell or capsule around them within 72 hours of implantation. Usually this capsule is soft and pliable and does not interfere with the look and feel of the implant. Over time, for reasons that are not entirely understood, this capsule can thicken and contract causing hardness, pain, and distortion of the position of the implant and consequently the shape of the breast. This can occur months or even years after the original procedure. Severe capsular contractions require re operation to incise or remove the capsule entirely and replace the implant. Costs of this additional surgery will be borne by the patient. Capsular contraction has been greatly reduced with the advent of smooth saline implants particularly those that are placed under the chest muscle.

Patient Initials \_\_\_\_\_

20. INCISION SITE, LOCATION, SIZE, SHAPE AND IMPLANT SIZE, SHAPE, POSITION, LOCATION, AND TYPE: Though these factors are discussed prior to surgery and every attempt is made to adhere to the patient's wishes as much as is prudent and reasonable, the patient agrees to whatever treatment or surgery is necessary, advisable or available at the time of and during the operation. Permission is granted for other incisions, implants or treatments as may be needed. No certain preconceived appearance or result can be obtained. Other incision sites may be needed later if there are problems especially with the underarm incision.

Patient Initials \_\_\_\_\_

21. 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. It may be necessary to wait several months before putting a new implant back in.

Patient Initials \_\_\_\_\_

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

of silicone gel on the body with a ruptured implant are unknown.

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23. **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 and 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.

Patient Initials \_\_\_\_\_

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

Patient Initials \_\_\_\_\_

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

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26. **LEAKING IMPLANTS AND DEFLATION:** Saline filled implants are expected to leak and deflate eventually. Though the saline is not harmful to the body, if the leakage and consequent 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.

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27. **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. Usually there is some numbness of the nipples from breast implant surgery. Most of the numbness goes away in a period of months or years. Some numbness may be permanent and unequal. There also may be hypersensitivity.

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28. **INTERFERENCE WITH MAMMOGRAPHY:** The presence of breast implants of any type interferes with mammography and 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 recommendations of the American Cancer Society should be followed for when to have mammography. ACS recommends that at age 35 to 40 a base line mammogram should be done. Between ages 40 and 50 mammograms should be done every one to two years. Women over fifty should have a mammogram every year. Mammograms should be done more

frequently when there is a family history of breast cancer.

Patient Initials\_\_\_\_\_

29. 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 Federal Drug Administration, September 26, 1991, "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."

Patient Initials\_\_\_\_\_

30. BREAST FEEDING: Many patients have become pregnant and have breast fed infants after breast implant surgery. Breast implants may interfere with breast feeding 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. It is possible that there could come some harm to the infant who is breastfed from breasts with implants. Potential harmful effects are unknown.

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31. AXILLARY (ARMPIT) INCISION: The axillary or armpit incision may cause more tenderness and discomfort after the operation, especially with movements of the arms, than the incisions on the breasts or chest wall. In addition, there may be numbness of the arms around the incision or of part of the upper arms, the forearms or the hands and fingers. There also could be interference with circulation of the upper arms or hands that may cause a tendency to have numbness, tingling or swelling of the hands. These problems are rare but could occur even when the surgery is perfectly performed. Another incision site may be necessary if there are problems at this surgery or a later surgery.

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32. BREAST CANCER AND IMPLANTS: Breast implants interfere with early detection of breast cancer. This could mean that women with breast implants have a reduced cure rate with breast cancer. Approximately two million American women have breast implants. While 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 implants are at increased risk. "Studies are still in progress and the results may not be known for many years to come.

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33. 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."

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34. STEROID ATROPHY: Steroids, such as cortisone, may be used in or around the breast implants at the time of surgery to prevent capsule contracture. Steroid atrophy may occur with thinning of the skin and the tissues around the implants. This may lead to a blue appearance around the border of the breast due to the visibility of the implant through the skin. The skin may stretch and the breasts may sag. Further surgery may be required if this occurs.

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35. 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 breasts cannot be made equal or alike.

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

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37. STRETCH MARKS OR STRIAE: Stretch marks, such as of the skin of the abdomen following pregnancy, may occur in the breasts. They may not occur until after pregnancy or many months or years later. The use of birth control pills may increase the tendency for stretch marks to appear following breast implant surgery.

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38. MUSCLE MOVEMENT: Implants that are placed below the pectoral muscle may move whenever the muscle is contracted with normal movements of the arms. This may cause a visible distortion of the appearance of the breasts with movement of the arms. Occasionally this movement is so distressing that further surgery is required to put the implants above the pectoral muscle.

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39. MUSCLE WEAKNESS: To place implants under the pectoral muscles, these muscles must be partially detached from their normal attachment to the ribs. Therefore, whenever the implants are placed below the pectoral muscles, there is some weakness of the muscle because of the surgical injury to the muscle itself or the nerve and blood supply to the muscle.

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40. DOUBLE FOLD OR BUBBLE DEFORMITY: A fold in addition to the new inframammary fold (the fold under the breast) may occur in the lower part of the breast. This is due to a persistence of the old inframammary fold or crease. It can cause a troublesome double bubble appearance that may or may not improve in time.

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41. IMPLANT DURATION: Implants last many 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 revise or replace the implants in the future.

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42. UNKNOWN RISKS: Although there are many risks that are known that can be described, most risks are still unknown.

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43. LONG TERM RISKS: According to the FDA " The two greatest concerns 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." FDA BG, Aug 1991.

Patient Initials \_\_\_\_\_

44. ADDITIONAL COSTS: 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 or prolonged illness, disability, hospitalization, disease, deformity, disfigurement and death. Any or all of these may require additional expenses and costs to the person having breast implant surgery or her family.

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45. ABNORMAL APPEARANCE OR FEEL: Implants are usually detectable. They may look or feel firmer. They may not move the same as normal breasts. The implants may be palpable or the implant valve may be palpable. They may look "stuck on", too high, too low or unequal.

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46. 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. I UNDERSTAND THAT MY RESULT MAY NOT BE LIKE ANY PICTURES OR DRAWINGS OR ANY PRECONCEIVED IDEA OR GOAL I MAY HAVE. There can be NO GUARANTEE that either I OR ANYONE ELSE WILL BE SATISFIED OR PLEASED WITH THE RESULT.

Patient Initials \_\_\_\_\_

### **Alternatives To Breast Enlargement with Implants**

Alternatives to breast enlargement with saline or silicone gel implants include repositioning of the nipple without breast enlargement (mastopexy), or no surgery at all.

### **Photographs**

I consent to be photographed before; during, and after the anticipated surgical procedure and that these photographs shall be the permanent property of Richard Fisher, MD and shall remain a part of my medical record.

I further consent  Yes  No that these photographs may be published in scientific journals, and or shown for scientific reasons, and or used for advertising purposes by Dr. Fisher in any venue of his choosing. This permission is without time limit and cannot be withdrawn. If photographs of me are used in this fashion, I will not be identified.

**DO NOT SIGN THIS CONSENT UNTIL YOU HAVE HAD ALL YOUR QUESTIONS ANSWERED TO YOUR SATISFACTION.**

*Informed Consent*

I have had sufficient time and opportunity to discuss my condition and proposed surgery with Dr. Fisher and all my questions have been answered to my satisfaction. I believe I have adequate knowledge on which to base an informed consent to the proposed treatment.

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Patient/Responsible Party

\_\_\_\_\_  
Date

*Physician Declaration:* I have explained the contents of this document to the patient and have answered all the patient's questions, and to the best of my knowledge, the patient has been adequately informed. The patient has consented.

\_\_\_\_\_  
Richard D. Fisher, MD

\_\_\_\_\_  
Date