

Dr. James B. Lowe - Plastic Surgery
BREAST IMPLANTATION SURGERY INFORMATION SHEET AND
INFORMED CONSENT

Instructions

This is an informed consent document that has been prepared to assist your plastic surgeon to inform you concerning breast implantation surgery, its risks, and alternative treatment.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for surgery as proposed by your plastic surgeon.

INTRODUCTION

Breast implants can be utilized clinically in patients for reconstructive and cosmetic purposes. Currently, it is important to note that all implants use a silicone outer shell. Saline implants are filled with sterile salt water and gel implants are filled with silicone gel. Gel implants are no longer restricted by the FDA for general use and can offer certain benefits for reconstructive and cosmetic purposes. Because of past FDA restriction, Dr Lowe will try to discuss the pros and cons associated with saline and gel implants.

Breast implants are composed of prosthetic material. Prosthetic material has a limited life span, a failure rate, and is prone to inflammatory processes such as capsular contracture and infection. Most implant manufacturers report implant failure rates in the range of 1-2% per year and a need to exchange the implant at 10 years. Different manufactures have different warranties for their implants that range between 5 to 10 years. If you decide to have implants it is important to keep surgical information about your implants in case of future concerns or recalls. Mandatory controlled research studies for gel implants are no longer required at this time.

ALTERNATIVE TREATMENT

Alternative forms of management consist of not undergoing the breast implant surgery. Cosmetic patients may elect not to have surgery after they have had a frank discussion with their Board Certified Plastic Surgeon. In reconstructive surgery there are a variety of alternative ways to create a breast that do not require prosthetic material. Risks and potential complications are associated with alternative forms of reconstructive surgery should be discussed before making a final decision.

RISKS OF BREAST IMPLANT SURGERY

With any type of activity there is inherent risk. 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 the following complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of breast implants.

Bleeding – It is possible, though unusual, that you may have problems with bleeding during or after surgery. Should postoperative bleeding occur, it may require emergency treatment to stop the bleeding or blood transfusion. Do not take any aspirin or anti-inflammatory medications for ten days before surgery, as this contributes to a greater risk of bleeding. Hypertension (high blood pressure) that is not under good medical control may cause bleeding during or after surgery. Accumulations of blood under the skin may delay healing and cause scarring.

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Infection – Infection is quite unusual after surgery. Should an infection occur, additional treatment including antibiotics or surgery may be necessary. If a breast implant becomes infected it will need to be removed for a period of time. In some cases a new implant may be contraindicated and a staged reconstructive procedure may be required to address resulting deformities. Infection is one of the most devastating complications associated with breast implantation. Infection rates following cosmetic surgery range between 1-2% and are much higher following breast reconstruction.

Scarring – Although good wound healing after a surgical procedure is expected, abnormal scars may occur both within the skin and deeper tissues. Scars may be unattractive and of different color than surrounding skin. Capsular contracture is a type of scar that forms around a breast implant that can result in pain or deformity. Capsular contracture is related to the type of implant, type of surgery, and associated complications. Capsular contracture is more common with gel implants. Bleeding, fluid, or radiation can contribute to capsular contracture and some patients may require surgery to address the problem. There is also the possibility of visible marks from sutures and additional treatments including surgery may be needed to treat scarring from the surgical site.

Damage to deeper structures – Deeper structures such as nerves, blood vessels, and muscles may be damaged during the course of surgery. The potential for this to occur varies with the type of breast implantation procedure performed. Injury to deeper structures may be temporary or permanent. Patients sometimes complain of loss of nipple sensation or hypersensitivity of the nipple following cosmetic breast implantation.

Numbness – There is the potential for permanent nipple or skin numbness after breast implantation. The occurrence of this is not completely predictable. Diminished (or loss of skin sensation) in the nipple area may not totally resolve in some patients in the range of 5-15%.

Asymmetry – The human breast is normally asymmetrical. There can be a variation from one side to the other following breast implant procedure. Slight asymmetry between following cosmetic implantation may be as high as 40%.

Chronic pain – Chronic pain may occur very infrequently after breast implantation.

Skin disorders/ breast cancer – Breast implantation is a surgical procedure used to shape the breast. Mammography must be modified following breast implant placement and some obstruction of the breast tissue during mammogram will result from implants placed in a normal breast. At this time there is no evidence that breast implant increase your risk of breast cancer. Skin disorders such as contact dermatitis are not uncommon following breast implantation, but it is usually resolves within several months.

Allergic reactions – In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during pregnancy and prescription medicines. Allergic reactions may require additional treatment or surgery.

Delayed healing – Wound disruption or delayed wound healing is possible. Some areas of the breast may not heal normally and may take a long time to heal. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue.

Long term effects – Subsequent alterations in breast appearance may occur as the result of aging, or other circumstances not related to breast surgery. The weight of breast implants will often cause your breast to sag over time. Future surgery or other treatments may be necessary to maintain the results of a breast implant operation.

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Size and Shape – Dr Lowe can not guarantee size or shape after breast implant surgery. Dr. Lowe will do his best to get an idea of the size of the implant you desire and to achieve a practical result. The fact is that there are technical restrictions and limits in implant technology that does not necessary allow the patient to always pick the size or shape. Going larger or smaller than the size of implant recommended will most likely have a detrimental effect on your surgical outcome and shape.

Surgical Technique - Cosmetic breast implantation can be performed using a variety of techniques. One technique may be better than another based on the situation. Dr. Lowe will recommend the technique that he feels will optimize your result taking into account the present and the future. If you elect to undergo a technique that is not recommended this may have a detrimental effect on your result.

Breast lift with Implant – When a breast implant is combined with a breast lift the operation becomes far more complex and expensive. The ultimate position of the implant and scar can not be fully determined. When these two procedures are combined two separate forces are in play (implant stretch and skin tightening). The skin will only allow a certain amount of tension without dying. Dr. Lowe will do his best to lift and enlarge the breast but over time you may want the skin envelope to be tighter. Often a second surgery is required in these situations at one year to optimize the results. A second operation or revision requires a separate fee and is not included in the original surgical quote.

Maintenance and follow-up – Breast implants pockets may stiffen and their position may change with time. Often Dr. Lowe will ask you to wear a breast strap or massage the implants to help with scarring or position. It is also important to notify the plastic surgery in timely fashion if the implant fails or a significant change occurs following surgery. Always keep a record of the type of implant that was placed in case of complications or recall. The implants will not last forever and will eventually rupture and often a capsule will become more significant over time. Patients should expect changes in technology and changes in approval for breast implant over time. It should be noted that exchanging breast implants in the future is often more complicated than the original surgery due to age and skin stretch. If you have concerns or fears related to gel implants it is best to avoid them even if the FDA has approved their general use. Breast implants are a long term commitment. After you have had breast implants for several months, it is usually hard to go back with a removal alone because the breast envelope has been significantly stretched by implantation.

Surgical anesthesia – Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

Shock- In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

Cardiac and Pulmonary Complications- Surgery, especially longer procedures, may be associated with the formation of, or increase in, blood clots in the venous system. 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 and fat 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 blood clots or swollen legs that may contribute to this condition. Cardiac complications are a risk with any surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

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ADDITIONAL ADVISORIES

Unsatisfactory Result- Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. There is the possibility of an unsatisfactory result from the breast implant surgery. This would include risks such as skin and soft tissue loss, wound disruption, chronic pain, poor healing, and loss of sensation. The surgery may result in unacceptable visible or tactile deformities, loss of function, or implant mal-position. Additional surgery may be necessary should the result be unsatisfactory. Surgeons attempt to place the implant symmetrically on the chest wall, but it is never perfect. In some cases nipples may not be symmetric before or after surgery.

Female Patient Information- It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you believe you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

Medications- There are many 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 which 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. 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.

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray)-

Patients who are currently smoking, use tobacco products, or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying, delayed healing, and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smokers may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication. Please indicate your current status regarding these items below:

_____ I am a non-smoker and do not use nicotine products. I understand the risk of second-hand smoke exposure causing surgical complications.

_____ I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired.

HEALTH INSURANCE

There is the possibility that surgery will result in a complication such as bleeding or fluid collection that require another operation or medical intervention. Most health insurance companies exclude coverage for cosmetic surgical operations or any complications that might occur from cosmetic surgery. If the procedure is performed for reconstructive purposes or because it is medically indicated it may be covered. Please carefully review your health insurance subscriber-information pamphlet.

ADDITIONAL SURGERY NECESSARY

There are many variable conditions in addition to risks and potential surgical complications that may influence the long term result from breast implant surgery. Even though risks and complications occur

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infrequently, the risks cited are particularly associated with breast implant surgery. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. Infrequently, it is necessary to perform additional surgery to improve your results.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, anesthesia, and possible outpatient hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan you will be responsible for necessary co-payment, deductibles, and charges not covered. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day surgery charges involved with reversionary surgery would also be your responsibility.

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). This 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 which is based on all the facts in your particular case and the 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 consent on the next page.

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CONSENT FOR SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr. James Lowe and such assistants as may be selected to perform the following procedure or treatment.

I have received the following information sheet:

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2. I recognize that during the course of the operations and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I, therefore, authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
5. I consent to the photographing or televising of the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices or body parts which may be removed.
8. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
9. **IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:**
 - A. The above treatment or procedure to be undertaken.
 - B. There may be alternative procedures or methods of treatment.
 - C. There are risks to the procedure or treatment proposed including those listed on pages above of the Informed Consent for Breast Implantation Surgery information sheet.
 - D. I have read, understood, and have had the opportunity to ask questions concerning the above, as well as the Informed Consent for Breast Implantation Surgery information sheet.
 - E. I am satisfied with the explanation.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9).

Patient or Person Authorized To Sign for Patient.

Date

Witness