

Dr. James B. Lowe - Plastic Surgery
BREAST IMPLANTATION SURGERY INFORMATION SHEET AND INFORMED
CONSENT (WITH MANUFACTURE'S ADDENDUM)

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 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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Blood clots / deep vein thrombosis – Breast reduction and breast lift operations usually require some time in the operating room. Although any operation can be associated with a blood clot in the legs, it is more common following more lengthy operations. It is important to note that birth control pills and other medications can increase your risk of this problem. After surgery patients must make every effort to be active and ambulate while in the hospital and at home. Deep vein thrombosis can be a potentially life threatening complication that may require further medical care and expense.

Fluid collections or Seroma – Fluid collections can form in the period following breast surgery. These collections are called “seromas” and may be prevented by the use of compression dressings or drains. If the patient develops a fluid collection it may require further treatments.

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.

Skin Contour Irregularities- Contour and shape irregularities may occur after breast surgery. 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 are always a possibility. This may improve with time, or it can be surgically corrected. Nipple retraction may occur after breast surgery.

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 removal.

Skin Discoloration / Swelling- Some bruising and swelling normally occurs following breast surgery. The skin in or near the surgical site can appear either lighter or darker than surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods of time and, in rare situations, may be permanent.

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%.

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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%.

Pain- You will experience pain after your surgery. A breast reduction may not improve musculoskeletal pain in the neck, back and shoulders. Pain of varying intensity and duration may occur and persist after surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue after a breast reduction.

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.

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

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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.

Inherent Risks of Saline & Silicone Gel-filled Breast Implants

Implants- Breast implants, similar to other medical devices, can fail. When a saline-filled implant ruptures, the saline material is absorbed by the body, but the shell material remains. 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). Rupture of a breast implant may or may not produce local firmness in the breast. Rupture can occur as a result of an injury, from no apparent cause (silent rupture), or during mammography. It is 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. Breast implants can wear out, they are not guaranteed to last a lifetime and future surgery may be required to replace one or both implants. A MRI (magnetic resonance imaging) study may be necessary to evaluate the possibility of implant rupture, yet it may not be 100% accurate in diagnosing implant integrity. Saline-filled breast implants may not have the same contour or feel as silicone-filled breast implants. The shape of your breasts after surgery depends on many factors such as your skin thickness, position, placement of the implants, and technique. You should discuss with your surgeon the possibility of a different and less than desirable contour-shape as well as feel of your result.

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Capsular Contracture- Scar tissue, which forms internally around the breast implant, can tighten and make the breast round, firm, and possibly painful. Excessive firmness of the breasts can occur soon after surgery or years later. The occurrence of symptomatic capsular contracture is not predictable. The incidence of symptomatic capsular contracture can be expected to increase over time. Capsular contracture may occur on one side, both sides or not at all. It is more common with implant placement in front of the chest muscle layer. Treating capsular contracture may require surgery, implant replacement, or implant removal. Capsular contracture may reoccur after these surgical procedures.

Implant Extrusion / Tissue Necrosis- Lack of adequate tissue coverage or infection may result in exposure and extrusion of the implant through the skin. Tissue breakdown (necrosis) has been reported with the use of steroid drugs, after chemotherapy/radiation to breast tissue, due to smoking, microwave diathermy, and excessive heat or cold therapy. In some cases, incision sites fail to heal normally. An implant may become visible at the surface of the breast as a result of the device pushing through layers of skin. If tissue breakdown occurs and the implant becomes exposed, implant removal may be necessary. Permanent scar deformity may occur.

Skin Wrinkling and Rippling- Visible and palpable wrinkling of implants and breast skin can occur. Some wrinkling is normal and expected with silicone gel-filled breast implants. This may be more pronounced in patients who have silicone gel-filled implants with textured surfaces or thin breast tissue. Palpable wrinkling and/or folds may be confused with tumors and some cases must be investigated.

Calcification- Calcium deposits can form in the scar tissue surrounding the implant and may cause pain, firmness, and be visible on mammography. Removal of calcifications around breast implants may require surgery to remove the capsule. 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.

Chest Wall Irregularities- Chest wall irregularities have been reported secondary to the use of tissue expanders and breast implants. Residual skin irregularities at the ends of the incisions are always a possibility when there is redundant skin. This may improve with time, or it can be surgically corrected.

Implant 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). Unusual techniques of implant placement may increase the risk of displacement or migration. Additional surgery may be necessary to attempt to correct this problem. It may not be possible to resolve this problem once it has occurred.

Surface Contamination of Implants- Skin oil, lint from surgical drapes, or talc may become deposited on the surface of the implant at the time of insertion. The consequences of this are unknown.

Unusual Activities and Occupations- Activities and occupations that have the potential for trauma to the breast could potentially break or damage breast implants or cause bleeding/seroma.

Silicone Gel Bleed - Over time, small amounts of silicone gel material can pass through the shell layer of the implant and coat the outside of the implant. The occurrence of gel bleed is not predictable. Patients undergoing Gel Implantation should consider reviewing our on-line information and links.

Mammography- Breast implants may make mammography more difficult and may obscure the detection of breast cancer. Any breast implant can impair the detection of breast cancer, regardless of the type of implant or where it is placed in relation to the breast. Implant rupture can occur from breast compression during mammography. Inform your mammography technologist of the presence of breast

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implants so that appropriate mammogram studies may be obtained. Patients with capsular contracture may find mammogram techniques painful and the difficulty of breast imaging will increase with the extent of contracture. Ultrasound, specialized mammography and MRI studies may be of benefit to evaluate breast lumps and the condition of the implant(s). 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. Patients may wish to undergo a preoperative mammogram and another one after implantation to establish a baseline view of their breast tissue. You may be advised to undergo a MRI study in the future to verify the condition of your breast implants inside your body.

Second-Generation Effects- A review of the published medical literature regarding the potential damaging effect on children born of mothers with breast implants is insufficient to draw definitive conclusions that this represents a problem.

Unsatisfactory Implant Result- Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. You may be disappointed with the results of surgery. Asymmetry in implant placement, displacement, nipple location, unanticipated breast shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Breast size may be incorrect. Unsatisfactory surgical scar location may occur. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. It may be necessary to perform additional surgery to improve your results, change implant size or remove and not replace implants.

Ruptured Breast Implants- As with any man-made object implanted in the human body, device failure can occur. It is possible that in patients who have silicone gel-filled implants 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.

Removal / Replacement of Breast Implants- Future revision, removal, or replacement of breast implants and the surrounding scar tissue envelope involves surgical procedures with risks and potential complications. There may be an unacceptable appearance of the breasts following implant removal.

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 and tissue expanders.

Capsule Squeeze Procedures- Closed capsulotomy, the process of forcefully squeezing the fibrous capsule around a breast implant to break up scarring is not recommended. This may result in rupture of the breast implant, gel migration, bleeding, or other complications.

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Large Volume Breast Implants- Patients who request an outcome of breast augmentation that produces disproportionately large breast size must consider that such a choice can place them at risk for a less than optimal long-term outcome and the need for re-operation and additional expenses. The placement of excessively-sized breast implants exceeds the normal dimensions of the breast, produce irreversible tissue thinning, implant drop out, and visible/palpable rippling.

Breast Implant Technology / Technologic Improvements in Breast Implants- The technology of breast implant design, development and manufacture will continue to progress and improve. Newer or future generations of implants may be better in some way from those currently available.

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

ADDITIONAL IMPLANT SURGERY NECESSARY (Re-operations)

There are many variable conditions that may influence the long-term result of placement of permanent breast implant. 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 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 placement of permanent breast implant following tissue expansion surgery. Other complications and risks can occur but are even more uncommon. 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. In some situations, it may not be possible to achieve optimal results with a single surgical procedure.

ADDITIONAL ADVISORIES

Breast Disease- Current medical information does not demonstrate an increased risk of breast disease, breast cancer, or recurrence of breast cancer in women who have had reconstructive breast surgery. Breast disease and breast cancer can occur independently of breast surgery. Individuals with a personal history or family history of breast cancer may be at a higher risk of developing breast cancer than a woman with no family history of this disease. It is recommended that all women perform regular self-examination of their breasts, have mammograms according to American Cancer Society guidelines, and seek professional care should a breast lump be detected.

Interference with Sentinel Lymph Node Mapping Procedures- Breast surgery procedures that involve cutting through breast tissue, similar to a breast biopsy, can potentially interfere with diagnostic procedures to determine lymph node drainage of breast tissue to stage breast cancer.

Breast and Nipple Piercing Procedures- Individuals who currently wear body-piercing jewelry in the breast region are advised that a breast infection could develop from this activity. Individuals with breast implants seeking to undergo body piercing procedures to the breast region must consider the possibility that an infection could develop anytime following this procedure. Should an infection occur, it is possible that it could spread to the breast implant space. 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. If an infection does not respond to antibiotics, the breast implant may have to be removed. Individuals who currently wear body-piercing jewelry in the breast region are advised that a breast infection could also develop.

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Pregnancy and Breast Feeding- There is no evidence that breast reconstruction surgery has any effect on fertility or pregnancy. However, little information exists concerning the effect of abdominal muscle transfer on labor and delivery. If a woman has undergone a mastectomy, it is unlikely that she would be able to breast feed a baby on the affected side.

Long-Term Results- Subsequent alterations in breast shape may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause, or other circumstances not related to your surgery. Breast sagginess may normally occur.

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 suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

Intimate Relations After Surgery- Surgery involves coagulating of blood vessels and increased activity of any kind may open these vessels leading to a bleed, or hematoma. Increased activity that increased your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery and control bleeding. It is wise to refrain from sexual activity until your physician states it is safe.

Radiation Therapy- Radiation therapy to the chest region before or after breast implantation with a saline or gel breast implant can produce unacceptable firmness or other long-term complications. Previous radiation can result in unpredictable results such as scarring, contour irregularities, delayed healing, or complete tissue or flap loss.

Gum, Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, 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, smoking 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.

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Medications- There are 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 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 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.

Mental Health Disorders and Elective Surgery- It is important that 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 disorders. Although individuals may benefit psychologically from elective surgery, effects on mental health cannot be accurately predicted.

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. It should also be noted that breast augmentation procedures for cosmetic reasons may impact your ability to keep or obtain health insurance coverage. Currently, some insurance carriers will charge more, exclude, or refuse coverage for patients undergoing breast augmentation procedures.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of 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:

INFORMED CONSENT for BREAST IMPLANTATION SURGERY

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

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ACKNOWLEDGMENT OF INFORMED DECISION

I understand that this patient brochure, "Important Information for Augmentation Patients About Mentor MemoryGel Silicone Gel-filled Breast Implants," is intended to provide the information regarding the risks and benefits of silicone gel-filled breast implants, both general and specific to Mentor's MemoryGel products. I understand that silicone breast implant surgery involves risks and benefits, as described in this brochure. I also understand that the long-term (i.e., 10-year) safety and effectiveness of silicone gel-filled breast implants continue to be stueied. I understand that reading and fully understanding this brochure is required, but that there also must be consultation with my surgeon.

By circling the correct response and signing below, I acknowledge:

- Y/N I have had adequate time to read and fully understand this brochure:
- Y/N I have had an opportunity to ask my surgeon any questions I may have about this brochure or any other issues related to breast implants or breast implant surgery;
- Y/N I have considered the alternatives to silicone breast implants and have decided to proceed with Silicone breast implant surgery;
- Y/N I have been advised to wait an adequate amount of time after reviewing and considering this information, before scheduling my silicone breast implant surgery; and
- Y/N I will retain this brochure, and I am aware that I may also ask my surgeon for a copy of this signed acknowledgement.

PATIENT (PRINT NAME)

SIGNATURE OF PATIENT*

DATED

*A patient must be at least 22 years old for primary and revision breast augmentation with silicone breast implants.

By my signature below, I acknowledge that:

- My patient has been given an opportunity to ask any and all questions related to this brochure, or any other issues of concern;
- All questions outlined above have been answered "Yes" by my patient;
- My patient has had an adequate amount of time before making her final decision; and
- Documentation of this Informed Decision will be retained in my patient's permanent record.

SIGNATURE OF SURGEON

DATED

Breast Augmentation Preferences and Choices

____ I understand that Dr. Lowe can achieve virtually any size breast that I choose, but he is limited by the characteristics of my tissues that we can't change. I also understand that the choices I make, particularly with respect to implant size, can affect the appearance of my breasts as I get older and can affect my risks of having complications or needing additional operations in the future.

Please initial one of the following with regard to the BREAST SIZE YOU DESIRE:

____ I want a MINIMAL amount of enlargement.

____ I want to be AS FULL AS I CAN BE AND ACHIEVE A NATURAL APPEARING BREAST THAT IS SAFEST FOR MY TISSUES LONG-TERM. I leave the choice of implant size to Dr. Lowe, and will accept the size that he feels is safest for my tissues long-term.

____ I want a SIZE BREAST—at least a ____ cup size AND at least ____cc implant.

____ I want a SIZE BREAST – in the range of _____ to ____ cc implant.

(Please fill in ALL blanks)

Please initial one of the following with respect to CHOICE OF BREAST SIZE AND RISK OF FUTURE PROBLEMS:

____ I WANT A BREAST SIZE THAT WILL HAVE THE LEAST CHANCE OF CAUSING FUTURE SAGGING, COMPLICAITONS, OR NEED FOR ADDITIONAL PROCEDURES SUCH AS A BREAST LIFT. I understand Dr. Lowe will choose an implant with the fullest breast that is safest long-term, unless I specify a smaller or larger breast. I leave the choice of implant size to Dr. Lowe based on his evaluation of my tissues and body proportions. I understand that Dr. Lowe cannot guarantee a cup size or shape following surgery.

____ I WANT A SPECIFIC BREAST SIZE, EVEN IF IT MIGHT BE LARGER THAN IDEAL FOR MY TISSUES. If I want a larger implant than Dr. Lowe feels is optimal for my tissues, I understand that I may not have a natural appearing breast. I am willing to accept responsibility for appearance and increased risks of reoperations, complications, deformities, and additional costs and time off work and normal activities in the future.

Please initial one of the following with respect to HOW YOU WOULD LIKE YOUR BREASTS TO LOOK:

IMPLANT STYLE I prefer: ____ Gel ____ Saline

IMPLANT SHAPE I prefer: ____ Shaped ____ Round

IMPLANT SHELL TYPE I prefer: ____ Textured ____ Smooth

IMPLANT MANUFACTURER I prefer: ____ Allergan ____ Mentor ____ Other: _____

____ I want Dr. Lowe to choose and will abide by his choice

IMPLANT SIZE I prefer:

____ I want an implant that contains at least _____cc of gel or saline (if you have an opinion). If I do not specify a number of cc's that I want in my implant, I am leaving the decision entirely up to Dr. Lowe, and I will accept his judgment regardless of my breast size following surgery.

____ I have no specific preference for the size in cc's in my breast implants, and I want Dr. Lowe to choose based on his evaluation of my tissues and proportions. If Dr. Lowe chooses the implant size, I will abide by his choice, understanding he used the implant size he feels is safe, without producing additional risks or tradeoffs.

Breast Implant Surgery

____ If, after surgery, for any reason I desire a different size implant, I understand and accept that I must specify the exact type and size of implant in cc's, and that I am responsible for all costs associated with changing my implants, including surgeon fees, anesthesia fees, lab costs, and surgical facility fees. Further, I will not expect Dr. Lowe to re-operate as a result of my requests for a larger or different implant.

IMPLANT POCKET LOCATION I prefer:

____ I prefer my implant be placed UNDER muscle. I have read, understand, and accept the tradeoffs of placing an implant under muscle.

____ I prefer my implant be placed ABOVE muscle. I have read, understand, and accept the tradeoffs of placing an implant above muscle, and I am aware I may see visible implant edges or other irregularities with this technique.

____ I do not have a preference for over or under muscle, and I want Dr. Lowe to choose according to my tissue requirements. I have read and fully understand the tradeoffs of placing an implant either over or under muscle.

INCISION LOCATION I prefer:

____ Under the breast ____ Around the areola ____ In the armpit

____ I would like Dr. Lowe to choose my incision location based on his assessment, and I will abide by his decision.

____ I have read all of Dr. Lowe's informational materials and have had an opportunity to visit with Dr. Lowe and his staff. I have had an opportunity to ask questions and have had all of my questions answered to my satisfaction.

PATIENT (PRINT NAME)

SIGNATURE OF PATIENT*

DATED

WITNESS (PRINT NAME)

SIGNATURE OF WITNESS*

DATED