Dr. James B. Lowe – Plastic Surgery BREAST RECONTRUCTION 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 reconstruction 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 reconstruction surgery is an operation frequently performed by plastic surgeons. Breast reconstruction is either "immediate" or "delayed." Most breast reconstruction is immediate or started on the day of your breast cancer operation. Breast reconstruction may need to be delayed if the margins are not clear or if radiation treatment is planned. In some cases patients may elect to delay the reconstruction for personal reasons. Breast reconstruction is something you want not something you absolutely need. If the risk or potential complications are too much for you at this point, delaying the operation may be the right choice.

A reconstructed breast is never as good as the original breast. It is a process that requires a minimum of three stages to achieve an optimal result. The first stage always involves creating a breast mound and subsequent stages involve refinement of the mound, nipple creation, and symmetry procedures. Future stages may be delayed by adjuvant treatments such as chemotherapy or radiation. Wound problems related to breast reconstruction may delay these adjuvant treatments in some cases.

Typically, mastectomy or breast cancer operation involves removal of the breast tissue, node testing, and nipple removal. A mastectomy is similar to removing the orange from an orange peel. The peel or the skin of your breast is left behind but the tissue beneath is removed. The remaining skin is very thin and unhealthy in most cases. The first stage of breast reconstruction is limited by the quality of the overlying skin and the options available for reconstruction.

Reconstruction of one breast is far less complex and offers more options than the reconstruction of both breasts. The three main ways a plastic surgeon creates a breast is with an implant or tissue expander, an implant with back muscle (Lat. Flap with implant), or abdominal tissue (TRAM Flap). Each of these procedures has different indications and risks, and each approach can be modified in a number of ways. The patient's age, weight, anatomy, previous surgeries, and health history often determine the procedure that is best for them.

Breast implant reconstruction alone is the Chevy Cavalier of breast reconstruction. It does not require a lot of time at the first stage but is fraught with complications in most cases. It provides bulk but is not considered very attractive due to visibility and palpability of the implant under very thin skin. The Lat. Flap with implant is the Cadillac of breast reconstruction, the first stage takes 3 hours and the hospital stay is 2-3 days. The results are excellent but an implant is required in most cases. The TRAM flap is the Rolls Royce of breast reconstruction. It can take 4-8 hours to perform on the first stage and the hospital stay averages 4-6 days. The TRAM can provide a natural appearing breast derived from fat from your abdominal wall.

The type of cancer operation and your cancer management is up to you and your cancer surgeon. The reconstructive procedures should be chosen only after a consultation with your plastic surgeon. Remember that there are a variety of approaches to breast reconstruction and you may want to seek a second opinion. Sometimes another consultation with Dr. Lowe is required to decide on the reconstructive option that is best for you. It is important to develop a trusting and honest relationship with your plastic surgeon because of the significant risk and time required to complete the task.

ALTERNATIVE TREATMENT

Alternative forms of management consist of not undergoing breast reconstruction surgery. These procedures are performed in an attempt to recreate a breast but will not provide functional improvements or extend life. Risks and potential complications associated with alternative forms of treatment can be discussed with Dr. Lowe as well.

RISKS OF BREAST RECONSTRUCTION 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 the risk that you have questions about with your plastic surgeon to make sure you understand the consequences of the breast reconstruction you choose.

<u>Bleeding</u> – 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 a trip back to the operating room. Certain breast reconstruction procedures such as TRAM Flaps may require blood thinners that increase the chance of bleeding. If you are already anemic or experience blood loss that threatens your health, you may need a 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.

<u>Fluid collections</u> – Fluid collections can form in the period following breast reconstruction. 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 multiple tapping, medical treatment, a new drain, or a trip back to the operating room. Seromas are associated with breast implants and Lat. Flap reconstructions.

<u>Infection</u> – Infection is unusual following breast reconstruction, but it is more common in some types of procedures. An implant placed beneath the skin following mastectomy is prone to infection particularly following radiation. The Lat. Flap can protect the implant from infection, and the TRAM flap does not require an implant. Should an infection occur, additional treatment including antibiotics may be necessary. If an implant becomes infected it will need to be removed for a period of time until the infection fully resolves.

<u>Scarring</u> – 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 a different color than surrounding skin. There is the possibility of visible marks from sutures. Additional treatments including surgery may be needed to treat scarring. The Lat. Flap will leave a scar on your back and the TRAM will leave a scar on your abdomen.

<u>Skin compromise</u> – Certain breast cancer operations are associated with significant skin undermining or injury. Breast skin is evaluated in the operating room and sick skin is often removed by the plastic

Initials 2 Rev. 2007

surgeon when indicated. In some cases, skin compromise will not become apparent until after surgery. Skin death on the breast or the flap may require local wound care or a trip back to the operating room. Skin separation may be the result of skin death, tension, or infection. Certain areas of the body are more prone to this problem than others (i.e. belly button, lower abdomen, breast skin).

<u>Damage to deeper structures</u> – 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 reconstruction. Injury to deeper structures may be temporary or permanent.

<u>Unsatisfactory result</u> – There is the possibility of an unsatisfactory result from breast reconstruction. The surgery may result in unacceptable visible or tactile deformity, loss of function, or structural malposition. You may be disappointed that the results of surgery do not meet your expectations and additional surgery may be necessary in these cases. There are limitations in breast reconstruction and the surgeon can never guarantee size or shape of the reconstructed breast.

<u>Numbness</u> – There is the potential for permanent numbness following breast reconstruction procedures. The occurrence of this is not predictable on the breast skin itself but always occurs on the flaps used to fill the defect. As nerves recover they may become hypersensitive or even painful.

<u>Asymmetry</u> – The human body is normally asymmetrical. It is impossible to achieve absolute symmetry with breast reconstruction. Dr. Lowe will do his best to achieve as much symmetry as possible during surgery. Some reconstructive procedures allow for better symmetry than others. For instance, if a breast implant is used to reconstruct your breast, it is very hard to match the opposite breast without another implant. Also, it is difficult to create a large or droopy breast, and a breast reduction or breast lift is often required on the opposite breast.

<u>Skin irregularity</u> – Skin irregularities, bumps, and areas of stiffness usually occur after breast reconstruction procedures. Most of these areas resolve with time but some irregularities may be permanent or require revision.

<u>Allergic reactions</u> – 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 and prescription medicines. Allergic reactions may require additional treatment.

<u>Delayed healing</u> – Wound disruption or delayed healing is possible. Some areas of the abdomen may not heal normally and may take a long time to heal. These areas may require frequent dressing changes or further surgery to remove the non-healed tissue.

Long term effects/ functional alterations – The breast that was removed or operated on will never be as good as it was prior to surgery. However, most women are glad they underwent breast reconstruction and would do it again. To make a pretty breast the plastic surgeon must "rob from Peter to pay Paul." A breast implant does not require donor tissue, but it is prone to infection, palpability, and deformation. When the Lat. Flap (back muscle) with implant is used the implant is protected appears more natural. Slight weakness in the shoulder will result from harvesting the back muscle. When the TRAM flap (abdominal muscle and fat) is used the abdominal wall is weakened and mesh is required to reconstruct the defect. This TRAM results in noticeable weakness in the lower abdomen with asymmetry and bulge. 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 breast reconstruction. Breast sagginess may normally occur.

Initials 3 **Rev. 2007**

<u>Weakness of Abdominal Muscle Function-</u> Following transfer of abdominal muscle or back muscle there is anticipated loss of normal function. Patients may notice a feeling of shoulder or abdominal weakness depending on the surgery performed while doing exercises or similar movements.

<u>Abdominal Wall Hernia</u>- On occasions, the area of the abdominal wall where tissue may be harvested for breast reconstruction will become weak and produce a hernia. Very rarely, re-operation for repair of this hernia may be necessary. In some cases, a plastic mesh will be inserted at the time of the breast reconstruction procedure incision closure to help support and reinforce the abdominal wall.

<u>Need for revision</u> – Certain breast reconstruction procedures are more likely to require revision surgery. Patient undergoing implantation or tissue expansion require the greatest amount of revision surgery. Patients undergoing TRAM reconstruction often require more revision surgery because of the abdominal scar. In some cases, it may be impossible to completely correct a complication.

<u>Recovery</u> - Changes may occur after breast reconstruction procedures that may limit a patient's function. Patients may recover at different rates following breast reconstruction surgery, but the more surgery you have done the more difficult the recovery. Typically, patients who undergo breast implantation go home the day after surgery with little functional limitation. Patients who undergo the Lat. Flap with implant typically require will require a 3-4 week recovery. It is far more difficult to recover from a TRAM flap and recovery averages 5-6 week recovery. The subsequent staged procedures usually require a very limited recovery.

<u>Surgical anesthesia</u> – General anesthesia involves risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation. If you are over 45 years of age, have a known medical condition, or you are in any way concerned about your health a pre-operative evaluation from your primary care physician or cardiologist is recommended prior to surgery.

<u>Shock-</u> 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.

<u>Pain-</u> You will experience pain after your surgery. 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 breast reconstruction.

<u>Thrombosed Veins</u>- Thrombosed veins, which resemble cords, occasionally develop in the area of the breast and resolve without medical or surgical treatment.

<u>Cardiac and Pulmonary Complications</u>. 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 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.

Initials 4 Rev. 2007

<u>Prosthetics / implants</u> – Anytime prosthetic material such as mesh or an implant is used it can become infected. If prosthetic material gets infected it must be removed. Implants do not last forever and need to be exchanged every 10 years in some cases. Implants can rupture or fail requiring exchange. Gel breast implants are filled with silicone jelly and or saline breast implants are filled with salt water. If you elect to have gel implants placed you can participate in a research protocol to track the device because safety concerns.

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 contourshape as well as feel of your result.

<u>Capsular Contracture-</u> 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 surgical procedures to treat this condition.

<u>Implant Extrusion / Tissue Necrosis-</u> 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 though 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 palpable tumors and questionable cases must be investigated.

Initials 5 Rev. 2007

<u>Calcification-</u> 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 requires capsulectomy surgery. 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.

<u>Chest Wall Irregularities</u>- 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 or "dog ears" are always a possibility when there is excessive redundant skin. This may improve with time, or it can be surgically corrected.

<u>Implant Displacement and Tissue Stretching</u>- 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.

<u>Surface Contamination of Implants-</u> 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.

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

<u>Silicone Gel Bleed</u> - 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.

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 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.

<u>Second-Generation Effects-</u> 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.

Initials 6 **Rev. 2007**

<u>Unsatisfactory Implant Result-</u> 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.

<u>Removal / Replacement of Breast Implants</u>- 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 removal of the implant.

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.

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 erythematosis, 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.

<u>Capsule Squeeze Procedures-</u> 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.

<u>Large Volume Breast Implants-</u> Patients who request an outcome of augmentation mammaplasty 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.

<u>Breast Implant Technology / Technologic Improvements in Breast Implants</u>. 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.

<u>Female Patient Information-</u> It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you suspect that you are pregnant. Many medications including

Initials 7 Rev. 2007

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

<u>Breast Disease-</u> 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.

<u>Interference with Sentinel Lymph Node Mapping Procedures-</u> 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.

<u>Pregnancy and Breast Feeding-</u> 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.

<u>Long-Term Results-</u> 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.

<u>Female Patient Information-</u> 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

Initials 8 Rev. 2007

may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

<u>Intimate Relations After Surgery-</u> 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.

<u>Radiation Therapy-</u> Radiation therapy to the chest region before or after breast reconstruction with a tissue expander/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.	1 understand	the risk of	second-hand
smoke exposure causing surgical complications.			
I am a smoker or use tobacco / nicotine product	s. I understar	nd 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.

<u>Medications-</u> 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 all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

ADDITIONAL SURGERY NECESSARY

Many variable conditions may influence the long-term result of breast reconstruction. Secondary surgery may be necessary to perform additional tightening or repositioning of the breasts. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications

Initials 9 Rev. 2007

occur infrequently, the risks cited are the ones that are particularly associated with breast reconstruction 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.

PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

HEALTH INSURANCE

Most insurance carriers consider breast reconstruction surgery a covered benefit. However, there may be additional requirements. Please review your health insurance subscriber-information pamphlet, call your insurance company, and discuss this further with your plastic surgeon. **Many insurance plans exclude coverage for secondary or revisionary surgery.**

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your surgeon, the cost of surgical supplies, anesthesia, laboratory tests, 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-payments, deductibles, and charges not covered. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revision surgery will also be your responsibility. In signing the consent for this surgery/procedure, you acknowledge that your have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including no surgery. The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. However, informed-consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information that is based on all the facts in your particular case and the current state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

Initials 10 Rev. 2007

CONSENT FOR SURGERY/PROCEDURE or TREATMENT

1.	I hereby authorize Dr 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 RECONSTRUCTION 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.	consent to the administration of such anesthetics considered necessary or advisable. I understant all forms of anesthesia involve risk and the possibility of complications, injury, and sometime eath.		
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, providing 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 at 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 above. D. I have read, understood, and have had the opportunity to ask questions concerning the above, as well as the Informed Consent Breast Reconstruction Surgery information sheet. E. I am satisfied with the explanation. 		
ΙC	ONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9).		
— Pat	cient or Person Authorized To Sign for Patient.		
— Da	te Witness		

Initials 11 **Rev. 2007**