Informed Consent

Breast Reconstruction with Tissue Expanders/Implants/Fat Latissimus Dorsi Muscle Flaps

INSTRUCTIONS

This is an informed consent document that has been prepared to help inform you about breast reconstruction with a tissue expander, its risks, as well as alternative treatment(s).

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 and agreed upon by you.

GENERAL INFORMATION

There are a variety of surgical techniques for breast reconstruction. Breast cancer patients who are candidates for breast reconstruction may consider tissue expander breast reconstruction, either immediately following mastectomy or at a later time. The best candidates, however, are women whose breast cancer, as far as can be determined, seems to have been eliminated by mastectomy and other treatments.

Breast reconstruction has no known effect on altering the natural history of breast cancer or interfering with other forms of breast cancer treatment such as chemotherapy or radiation.

Breast reconstruction with implants can be a one or two – stage process. Direc to implant reconstruction is a one – stage process, although needs for secondary revision are high. Reconstruction with tissue expansion is a **two-stage** process. It first involves the use of a silicone rubber balloon-like tissue expander that is inserted beneath the skin and often also beneath chest muscles. Saline or air is gradually injected into the tissue expander to fill it over a period of weeks or months. This process allows the skin on the chest to be stretched over the expander, creating a breast mound. In most cases, once the skin has been stretched enough, the expander is surgically removed and replaced with a permanent breast implant. Some tissue expanders are designed to be left in place as a breast implant.

There are legitimate reasons to delay breast reconstruction. Some women may be advised by their surgeon or oncologist to wait until other forms of necessary cancer treatment are completed or disease staging has been accomplished. Other patients may require more complex breast reconstruction procedures. Women who smoke or who have other health conditions such as obesity may be advised to postpone surgery. Individuals with a weakened immune system (currently receiving chemotherapy or drugs to suppress the immune system), conditions that interfere with blood clotting or wound healing, or have reduced blood supply to the breast tissue from prior surgery or radiation therapy treatments may be at greater risk for complications and poor surgical outcome. In any case, being informed of your options concerning breast reconstruction can help you prepare for a mastectomy with a more positive outlook on the future.

The shape and size of your breasts prior to surgery will influence both the recommended placement of the tissue expander and the final shape of your reconstructed breast. Tissue expander breast reconstruction cannot produce an exact replica of the removed breast. Breast symmetry surgery on the opposite breast may be needed to produce a similar size. The nipple and darker skin surrounding it, called the areola, may be reconstructed in a subsequent procedure after the breast mound is created through tissue expansion.

Since May 2000, saline-filled breast implants and tissue expander devices have been approved by the United States Food and Drug Administration (USFDA) for use in breast augmentation and reconstruction. The FDA approved silicone gel implants for use in breast augmentation and reconstruction in November 2006.

Patients undergoing breast surgery with tissue expanders and implants must consider the following:

- Breast augmentation or reconstruction with implants may not be a one-time surgery.
- Breast implants and tissue expanders of any type are not considered lifetime devices. They cannot be expected to last forever. You will likely require future surgery for implant replacement or removal.
- Changes that occur to the breasts following augmentation or reconstruction with implants are not reversible. There may be an unacceptable appearance to the breast if you later choose to have breast implants or tissue expanders removed.

Breast implant surgery is contraindicated in women with untreated breast cancer or pre-malignant breast disorders, active infection anywhere in the body, or individuals who are currently pregnant or nursing.
Individuals with a weakened immune system (currently receiving chemotherapy or drugs to suppress the immune system), conditions that interfere with blood clotting or wound healing, or reduced blood supply to the breast tissue from prior surgery or radiation therapy treatments may be at greater risk for complications and poor surgical outcomes.

Liposuction is a surgical technique to remove unwanted deposits of fat from specific areas of the body, including the face and neck, upper arms, trunk, abdomen, buttocks, hips and thighs, and the knees, calves, and ankles. This is not a substitute for weight reduction, but a method for removing localized deposits of fatty tissue that do not respond to diet or exercise. Liposuction may be performed as a primary procedure for body contouring or in combination with other surgical techniques such as facelift, abdominoplasty, or thigh lift procedures to tighten loose skin and supporting structures.

The best candidates for liposuction are individuals of relatively normal weight who have excess fat in particular body areas. Having firm, elastic skin will result in a better final contour after liposuction. Skin that has diminished tone due to stretch marks, weight loss, or natural aging will not reshape itself to the new contours and may require additional surgical techniques to remove and tighten excess skin. Body-contour irregularities due to structures other than fat cannot be improved by this technique. Liposuction by itself will not improve areas of dimpled skin known as "cellulite."

Liposuction, also called Suction-assisted lipectomy, is a surgical procedure performed by using a hollow metal surgical instrument known as a cannula that is inserted through small skin incision(s) and is passed back and forth through the area of fatty deposit. The cannula is attached to a vacuum source, which provides the suction needed to remove the fatty tissue.

In some situations, a special cannula may be used that emits ultrasonic energy, laser energy, or a jet of water to break down fatty deposits. Depending on your needs, your surgeon may recommend suction-assisted lipectomy alone, or in combination with another technique.

A variety of different techniques are used by plastic surgeons for the liposuction procedure and care following surgery. Liposuction may be performed under local, sedation, or general anesthesia. Tumescent liposuction technique involves the infiltration of fluid containing dilute local anesthetic and epinephrine into areas of fatty deposits. This technique can reduce discomfort at the time of surgery, blood loss, and postoperative bruising.

Compression support garments and dressings are worn to control swelling and promote healing.

A person's own fat may be used to improve the appearance of the body by moving it from an area where it is less needed (usually the thighs or abdomen) to an area that has lost tissue volume due to aging, trauma, surgery, birth defects, or other causes. Typically, the transferred fat results in an increase in volume of the breast. Before the procedure, the areas from where the fat is being removed may be injected with a fluid to minimized bruising and discomfort. The fat may be removed from the body by a narrow surgical instrument (cannula) through a small incision or may be excised (cut out) directly through a larger incision. In some cases, the fat may be prepared in a specific way before being replaced back into the body. This preparation may include the washing, filtering, and centrifugation (spinning) of the fat. The fat is then placed into the desired area using either a smaller cannula or needle, or it may be placed directly through an incision or puncture holes. Since some of the fat that is transferred does not maintain its volume over time, your surgeon may inject more than is needed at the time to achieve the desired end result. Over a few weeks, the amount of transferred fat will decrease. In some cases, more fat may need to be transferred to maintain the desired results. Fat transfer procedures may be done using a local anesthetic, sedation, or general anesthesia depending on the extent of the procedure.

Fat Transfer to the Breasts:

Fat transfer has been used to improve the appearance of breasts reconstructed after cancer treatment, to improve the appearance of breast deformities, and to enlarge breasts for cosmetic purposes. While there is limited information regarding the long-term implications of such procedures, there are some potential concerns, especially with regard to breast cancer detection. Since the transferred fat may become firm and cause lumps, it may be necessary to undergo radiological studies (mammogram, ultrasound, or MRI) to confirm that these lumps are not due to cancer. It is also possible that the firmness may make it more difficult for you or your doctor to examine the breasts. It is also possible that a biopsy may be needed if there is concern about any abnormal findings in your breasts. However, there is no reason to believe at this time that fat transfer procedures may cause breast cancer.

Fat transfer to the breast for cosmetic augmentation may require additional surgical procedures to obtain your desired breast size. A limited amount of fat can be injected during each surgical procedure to maintain viability. Sometimes, adjuvant devices (Brava) are recommended to assist in this process.

Capsulectomy is a surgical operation performed to treat scarring that occurs around breast implants or to revise the shape of the pocket where the implant is placed. This involves surgical cutting and removal of scar tissue that forms around a breast implant and usually the placement of new breast implant(s).

It is normal for scar tissue to form internally around a breast implant. In some patients, this scar tissue may tighten and make the breast round, firm, and possibly painful. Excessive firmness of the breasts can occur soon after the original surgery or years later. The causes of capsular contracture are not fully understood. 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. Calcification can occur within the scar tissue that surrounds breast implants. Treatment for capsular contracture may require surgery, removal of the capsule layer, implant replacement, or implant removal. Patients may elect to increase or decrease the size of their breast implants.

Individuals with old, damaged, or broken implants (either saline or silicone gel-filled) may consider capsulectomy surgery and replacement with silicone gel-filled implants to maintain the long-term results from their original surgery, whether for cosmetic or reconstructive purposes. You may be advised by your surgeon to consider replacing your breast implants with new ones, irrespective of how long you have had them. In some situations, you may be advised to consider breast implants with a textured outer surface or to consider a different type of implant. Patients undergoing capsulectomy surgery and breast implant exchange must consider the possibility of future revisionary surgery. Breast implants do not have an indefinite lifespan and will probably require surgery for removal and/or replacement.

Depending on the extent of the scarring, it may be necessary to place the implant in a different location: partially underneath the pectoralis muscle on the chest, in front of the pectoralis muscle if the original placement was behind the muscle, or completely or partially, known as a “dual plane.” Incisions for the capsulectomy may be placed in locations that are different from those used in the original surgery. If the breasts are not the same size or shape before surgery, it is unlikely that they will be completely symmetrical afterward. Conditions that involve sagging of the breast or diminished skin tone (stretch marks) may require additional surgical procedures (breast lift/mastopexy) to reposition the nipple and areola upward and to remove loose skin. Additional procedures to internally tighten or reshape the implant pocket may be needed to reposition implants.

Patients who are considering secondary surgery to revise or maintain their results from breast implant surgery must know that additional surgery may not correct or improve their results.

Removal of breast tissue or top surgery mastectomy is a surgical procedure to remove breast tissue and create a more masculine contour to the chest. This operation also reduces the size of the areola, the darker skin around the nipple. The best candidates for top surgery mastectomy are healthy, emotionally stable trans men who are transitioning and have persistent, well-documented gender dysphoria, and who have realistic expectations about what this type of surgery can accomplish. If significant medical or mental health are present, they should be reasonably controlled prior to surgery. Breasts of any size can be removed. Mastectomy does leave permanent, noticeable scars on the chest. This procedure is irreversible, and thus permanent. There are a variety of different surgical techniques used for the removal of the breast tissue and recontouring of the chest.

Breast reconstruction has no known effect on altering the natural history of breast cancer or interfering with other forms of breast cancer treatment such as chemotherapy or radiation. However, breast reconstruction techniques and results may be affected by the administration of other forms of breast cancer treatment.

In breast reconstruction with the latissimus dorsi, a muscle located on the back along with its attached skin (and some intervening fat) is transferred to the chest region for the breast reconstruction procedure. The muscle flap maintains its own blood supply, and helps nourish the tissue that is transferred to the chest wall region. There are several variations on the surgical technique of latissimus muscle flap breast reconstruction, including microvascular surgery to attach the flap to the chest region. In many cases, your plastic surgeon may recommend that a breast implant be inserted underneath the muscle flap to give the breast mound additional projection. Many patients do not have enough soft tissue overlying the muscle to have sufficient projection without an implant, but this depends on the patient’s body frame and breast size as well.

Muscle flap techniques of breast reconstruction are useful in the following situations:

- Inadequate chest wall tissue for breast reconstruction with implants or expanders
- Past history of radiation to chest wall after mastectomy
- Patient with concerns about breast implants, although implants may be necessary to achieve symmetry
- Failure of earlier breast reconstruction

Contraindications to latissimus muscle flap breast reconstruction procedure include:

- A patient who is medically or psychologically unsuitable for breast reconstruction
- Previous injury to the latissimus muscle or local blood supply from surgery or other treatments

ALTERNATIVE TREATMENTS

Breast reconstruction with tissue expander is an elective surgical operation. Alternative treatments include the use of external breast prostheses or padding, breast reconstruction without tissue expansion, or the transfer of other body tissues for breast reconstruction. Potential risks and complications are associated with alternative surgical forms of treatment.

Latissimus muscle flap breast reconstruction is an elective surgical operation. Alternative treatments include the use of external breast prostheses or padding, tissue expansion breast reconstruction, breast implants, or the transfer of other body tissues for breast reconstruction.

Potential risks and complications are associated with alternative techniques of breast reconstruction that involve surgery.

INHERENT RISKS OF BREAST RECONSTRUCTION WITH IMPLANTS

Every surgical procedure involves a certain amount of risk, and it is important that you understand the risks involved with breast reconstruction with tissue expander. In addition, every procedure has limitations. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. While the majority of women do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of breast reconstruction with tissue expander.

Problems associated with breast implants and tissue expanders can be inherent to this type of implanted medical device or relate to complications of a surgical procedure. Patients considering surgery that involves breast implants and tissue expanders should review additional advisory information regarding this subject. Additional information concerning breast implants and tissue expanders may be obtained from the FDA, package-insert sheets supplied by the device manufacturer, or other information pamphlets required by individual state laws.

While every patient experiences her own individual risks and benefits following tissue expander breast reconstruction, clinical data suggests that most women will be satisfied with the outcome of surgery despite the occurrence of problems inherent with breast implant and tissue expander surgery.

SPECIFIC RISKS OF BREAST RECONSTRUCTION WITH IMPLANTS

Implants:

Implants and tissue expanders, similar to other medical devices, can fail. Tissue expanders can break or leak. When a saline-filled tissue expander ruptures, the body absorbs the saline material, but the shell material remains. Rupture can occur because of an injury, from no apparent cause (silent rupture), or during mammography. It is possible to damage a tissue expander at the time of surgery or subsequently with a needle during the insertion of saline into the device for purposes of inflation. Damaged, leaking, or broken tissue expanders cannot be repaired and require replacement or removal. The shape of your breasts after surgery depends on many factors such as your skin thickness, position, placement of the implants or expanders, and technique. You should discuss with your surgeon the possibility of a different and less than desirable contour or shape as well as feel of your result.

Rupture can occur as a result of an injury, from no apparent cause, or during mammography. The rupture of a silicone breast implant is most often undetected (silent rupture). It is possible to damage an implant at the time of surgery. Damaged or broken implants cannot be repaired. According to the FDA, ruptured or damaged implants require replacement or removal. Breast implants can wear out, as 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 is advised to evaluate the possibility of implant rupture, yet it may not be 100% accurate in diagnosing implant integrity. It should be noted that the FDA recommends regular MRI examinations. Specifically, patients are advised to follow the recommendations for serial MRI examinations, starting at three years after surgery and then every two years thereafter. Patients may be responsible for the associated costs.

Capsular Contracture:

Scar tissue, which forms internally around the tissue expander, 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 tissue expander placement in front of the chest muscle layer (in the "prepectoral" position). Treatment for capsular contracture may require surgery, tissue

expander replacement, or tissue expander removal. Capsular contracture may reoccur after surgical procedures to treat it. Some surgeons believe that preventative antibiotics during dental work and treatment for sinus infections and urinary tract infections may decrease its incidence. Discuss this with your surgeon.

Implant Extrusion/Tissue Necrosis:
Lack of adequate tissue coverage or infection may result in exposure and extrusion of the tissue expander or 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. Atrophy of breast tissue may occur. A tissue expander or 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 tissue expander or implant becomes exposed, removal may be necessary. Permanent scar deformity may occur.

Change in Nipple and Skin Sensation:
Breast reconstruction will not likely restore normal sensation to the breast or nipple. Changes in sensation may affect sexual response or the ability to breastfeed a baby.

Skin Wrinkling and Rippling:
Visible and palpable wrinkling of implants or tissue expanders and breast skin can occur. Some wrinkling is normal and expected. This may be more pronounced in patients who have saline-filled implants with textured surfaces or thin tissue. It may be possible to feel the tissue expander fill valve. Some patients may find palpable valve and wrinkles cosmetically undesirable. A palpable valve, wrinkling, and/or folds may be confused with palpable tumors and questionable cases should be investigated.

Calcification:
Calcium deposits can form in the scar tissue surrounding the tissue expander and may cause pain or firmness, and may be visible on mammography. These deposits must be identified as different from calcium deposits that are a sign of breast cancer. If this occurs, 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 or “dog ears” are a possibility when there is excessive 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 or tissue expander 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 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:
Skin oil, lint from surgical drapes, or talc may become deposited on the surface of the tissue expander or 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 a tissue expander or implant or cause bleeding/seroma.

Magnetic Resonance Imaging Examination During the Expansion Period:
Most of the expanders have a magnet at the injection site to allow for easier localization of the injection port during the expansion period. MRI uses very strong magnetic fields that may cause movement, heating, or dislocation of the expander. For this reason, patients with a breast tissue expander in place should not undergo MRI until the expander is removed and replaced with an implant.

Use of Acellular Dermal Matrix:
To place the expander in the right position and maintain that position, your plastic surgeon may choose to use biological materials. Most commonly, these materials are derived from human cadaver skin or pig skin. These materials are generally processed and do not carry any viable cells. You should ask your surgeon about these materials. They assist in contouring

the pocket around the implant, provide additional cover to an implant, and become populated with your cells to become similar to your own tissue. These acellular products may produce fluid and require drains for a prolonged period.

Anaplastic Large Cell Lymphoma (ALCL):

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a very rare type of lymphoma that can develop in the scar capsule near saline or silicone breast implants. This very rare disease is currently being investigated as to its relationship with breast implants. The family of ALCL is an extremely rare cancer of the immune system, which can occur anywhere in the body. Based on adverse event reports, the United States Food and Drug Administration (FDA) estimates the total number of US cases of BIA- ALCL to be up to 250 cases. A predominance of BIA-ALCL patients have been noted to have a history of a textured-surface device. An exact single-number estimate of the risk for both textured and non-textured implants is not possible with the currently available data. Lifetime risk of BIA-ALCL has been estimated to be between 1:1,000 and 1: 30,000 women with textured breast implants, and BIA-ALCL risk is currently under investigation. BIA-ALCL usually involves a swelling of the breast, on average 3 to 14 years after the operation to insert the breast implant. Most cases were cured by removal of the implant and capsule surrounding the implant; however, rare cases have required chemotherapy and/or radiation therapy for treatment.

Patients with breast implants should be followed by a surgeon over time and seek professional care for implant-related symptoms such as pain, lumps, swelling, or asymmetry. Patients should monitor their breast implants with routine breast self-exams and follow standard medical recommendations for imaging (e.g., mammography, ultrasound, MRI). Abnormal screening results or implant-related symptoms may result in additional costs and expenses for tests and/or procedures to properly diagnose and treat your condition. Tests and procedures could include, but may not be limited to, obtaining breast fluid or tissue for pathology and laboratory evaluation, surgery to remove the scar capsule around the breast implant, implant removal, or implant replacement.

Breast Cancer:

Current medical information does not demonstrate an increased risk of breast cancer in women who have tissue expander surgery. A woman 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 periodic self-examination of their breasts, have mammography according to American Cancer Society guidelines, and seek professional care if a breast lump is detected. If suspicious tissue is identified prior to or during breast surgery, additional tests and therapy with corresponding expenses may be warranted.

Use of Drains:

During your surgery, your doctor may find it necessary to place drain(s). A drain is a small tube that drains fluid out from the area that was operated on. You will be instructed on the use of your drain. Placement of the drain may require a small separate incision. The drain will be removed when your doctor feels it is no longer necessary. The drain site may be closed at the time of drain removal. Closing the drain site may require special surgical tape or sometimes a suture. Your doctor may leave the site open to drain any residual fluid under the wound.

SPECIFIC RISKS OF LIPOSUCTION SURGERY

Patient Selection:

Individuals with poor skin tone, medical problems, obesity, or unrealistic expectations may not be candidates for liposuction.

Liposuction in General:

There is a possibility that large volumes of fluid containing dilute local anesthetic drugs and epinephrine that is injected into fatty deposits during surgery may contribute to fluid overload or a systemic reaction to these medications. Additional treatment including hospitalization may be necessary.

Ultrasound-, VASER-, & Laser-Assisted Lipectomy:

Risks associated with these techniques include the above-mentioned risks and the following specific risks:

Burns:

Energy may produce burns and tissue damage either at the location where the cannula is inserted into the skin or in other areas if the cannula touches the undersurface of the skin for prolonged periods of time. If burns occur, additional treatment and surgery may be necessary.

Cannula Fragmentation:
Ultrasonic energy produced within the cannula may cause disintegration (fragmentation) of the surgical instrument. The occurrence and effect of this is unpredictable. Should this occur, additional treatment including surgery may be necessary.

Unknown Risks:
The long-term effect on tissue and organs to exposure to short-duration, high-intensity ultrasonic energy is unknown. There is a possibility that additional risk factors of ultrasound-assisted liposuction may be discovered.

SPECIFIC RISKS OF FAT TRANSFER TO THE BREAST PROCEDURES

Change in Appearance:
Typically, the transferred fat loses some of its volume over time and then becomes stable. It is possible that more treatments may be needed to maintain the desired volume of the transferred fat and resulting appearance. Less commonly, if you experience significant weight gain, the transferred fat may increase in volume and cause an undesirable appearance. It is important to understand that more than one treatment may be needed and to discuss with your surgeon the costs associated with repeat treatments.

Firmness and Lumpiness:
While most transferred fat results in a natural feel, it is possible that some or all of the fat may become firm, hard, or lumpy. If some of the fat does not survive the transfer, it may result in fat necrosis (death of transferred fat tissue), causing firmness and discomfort or pain. Cysts may also form at the site of the transferred fat. Surgery may be required to improve such conditions.

Under- or Over-Correction:
The transfer of fat may not achieve the desired outcome. The amount of correction may be inadequate or excessive. It may not be possible to control the process of fat transfer due to factors attributable to each patient's situation. If under-correction occurs, you may be advised to consider an additional fat transfer procedure. If over-correction occurs, other surgical procedures such as liposuction or excision of the fat may be required.

Asymmetry:
Symmetrical body appearance may not result from a fat transfer procedure. Factors such as skin tone, fatty deposits, bony prominence, and muscle tone may contribute to normal asymmetry in body features. It may not be possible to achieve or maintain exact symmetry following fat transfer.

Long-Term Effects:
Subsequent changes in the shape or appearance of the area where the fat was removed or placed may occur as the result of aging, weight loss or gain, or other circumstances not related to the fat transfer procedure.

Combined Procedures:
Fat grafting is safe to be performed with other surgical procedures such as breast augmentation, revision breast surgery, and breast reconstruction. There are many other surgical procedures where fat transfer may be incorporated, including facelifts, abdominoplasty, liposuction, the treatment of open wounds, scleroderma, ulcers, and scars, to name just a few.

Seroma:
Fluid may accumulate between the skin and the underlying tissues following surgery, trauma, or vigorous exercise, which is referred to as a seroma. You may notice an increase in the fat graft area, localized swelling, or a shape change that should alert you that a seroma may have occurred in your postoperative period. Seromas should be addressed to prevent an unfavorable outcome. Should this problem occur, notify your surgeon and additional procedures for the drainage of fluid may be required.

Donor Sites:
The removal of fat in the process of fat transfer is often advantageous. The common complications from liposuction can occur at your donor site. Folds, wrinkles, or creases could occur. Some patients may have inadequate donor sites for fat grafting. Typically, these are patients who have had a previous liposuction procedure.

Fat Necrosis:
Fat that is transferred may not survive. Fatty tissue found deep in the skin might die. Fat necrosis may produce areas of firmness within the skin, hard lumps, localized tenderness/pain, or skin contracture. Calcifications and oil cysts may occur. Additional surgery to remove areas of fat necrosis may be necessary. There is a possibility that contour irregularities in the skin may result from fat necrosis.

Accidental Intra-Arterial Injection:
Extremely rarely, fat may be accidentally injected into arterial structures during the course of injection and produce a blockage of blood flow. The risks and consequences of accidental intravascular injection of fillers are unknown and not predictable.

Serious Complications:
Although serious complications have been reported to be associated with fat transfer procedures, these are rare. Such conditions include, but are not limited to, fat embolism (a piece of fat may find its way into the blood stream and result in a serious or life threatening condition), stroke, meningitis (inflammation of the brain), serious infection, blindness or loss of vision, or death.

SPECIFIC RISKS OF BREAST RECONSTRUCTION WITH LATISSIMUS MUSCLE FLAP SURGERY

Seroma:
Pockets of tissue fluid sometimes develop either in the back, under the arm, or under the chest wall after a latissimus muscle flap breast reconstruction. Additional procedures to drain this fluid accumulation may be necessary. Drainage procedures may need to be repeated frequently until the seroma resolves, and less commonly, surgical treatment may be required.

Change in Skin Sensation:
Breast reconstruction cannot restore normal sensation to your breast or nipple. Skin that is transferred as part of the muscle flap will lack sensation. Numbness may occur in the skin on the back where the latissimus muscle was located.

Delayed Healing and Loss of Flap:
Wound disruption or delayed wound healing is possible. It is possible to have areas of the chest wall tissue or latissimus muscle flap die. This may require frequent dressing changes or further surgery to remove the nonliving tissue. Some areas of the chest or muscle flap skin may heal abnormally or slowly when there is reduced blood supply to tissue from prior surgery or radiation therapy treatments.

Fat Necrosis:
Fatty tissue found in the flap may die. This may produce areas of firmness within the flap. Additional surgery to remove areas of fat necrosis may be necessary. There is a possibility of contour irregularities in the flap from fat necrosis.

Firmness:
Excessive firmness of the breast can occur after surgery due to internal scarring or scarring around a breast implant if one is used. The occurrence of this is not predictable and additional treatment or surgery may be necessary. Radiation therapy to the chest region after breast reconstruction with a latissimus muscle flap may produce substantial firmness or other long-term complications.

Breast Implants:
Risks associated with the potential use of breast implants are covered in a separate informed consent form.

Implant Extrusion:
Lack of adequate tissue coverage may result in exposure and extrusion of a breast implant if it is used in addition to the latissimus muscle flap. If tissue breakdown occurs and the breast implant becomes exposed, removal is usually necessary. It may not be possible to place a new implant at the same time. You may have to allow for complete wound healing without an implant before your breast reconstruction can be completed.

Asymmetry:
Some breast asymmetry naturally occurs in most women. Differences in breast and nipple shape, size, or symmetry may also occur after surgery. Additional surgery may be necessary to correct asymmetry after a breast reconstruction with latissimus muscle flap.

Loss of Latissimus Muscle Function:
There is anticipated loss of normal function in the latissimus muscle after it is transferred to the chest wall. Weakness in movements of the shoulder and upper arm can occur.

Unsatisfactory Result:
You may be disappointed with the results of breast reconstruction surgery. Asymmetry may occur after surgery in terms of muscle flap placement or breast shape and size. You may be dissatisfied with the flap placement or location of the surgical scar. It may be necessary to perform additional surgery to improve your results. Breast reconstruction by any technique may fail due to complications attributable to the mastectomy surgery or from chemotherapy/radiation therapy treatments, which are independent of the latissimus muscle flap procedure. Unsatisfactory results may NOT improve with each additional treatment.

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 reconstructive breast surgery. A woman 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 periodic self-examination of their breasts, have mammography according to American Cancer Society guidelines, and seek professional care if a breast lump is detected. If suspicious tissue is identified prior to or during breast surgery, additional tests and therapy with corresponding expenses may be warranted.

Use of Drains:
During your surgery, your doctor may find it necessary to place drain(s). A drain is a small tube that drains fluid out from the area that was operated on. You will be instructed on the use of your drain. Placement of the drain may require a small separate incision. The drain will be removed when your doctor thinks it is no longer necessary. The drain site may be closed at the time of drain removal. Closing the drain site may require special surgical tape or sometimes a suture. Your doctor may leave the site open to drain any residual fluid under the wound.

SPECIFIC RISKS OF BREAST IMPLANT REMOVAL SURGERY

Skin Wrinkling and Rippling:
Visible and palpable wrinkling of breast skin can occur. This may require additional surgery to tighten loose skin following breast implant removal surgery.

Ruptured Silicone Gel-Filled Breast Implants:
As with any manmade object implanted in the human body, device failure can occur. It is possible 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. The implant shell material of textured breast implants may be impossible to remove completely. 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.

GENERAL RISKS OF SURGERY

Healing Issues:
Certain medical conditions, dietary supplements, and medications may delay and interfere with healing. Patients with massive weight loss may have a healing delay that could result in the incisions coming apart, infection, and tissue changes resulting in the need for additional medical care, surgery, and prolonged hospitalizations. Patients with diabetes or those taking medications such as steroids on an extended basis may have prolonged healing issues. Smoking will cause a delay in the healing process, often resulting in the need for additional surgery. There are general risks associated with healing such as swelling, bleeding, possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, not meeting patient goals and expectations, and added expense to the patient. There may also be a longer recovery due to the length of surgery and anesthesia. Patients with significant skin laxity (patients seeking facelifts, breast lifts, abdominoplasty, and body lifts) will continue to have the same lax skin after surgery. The quality or elasticity of skin will not change and recurrence of skin looseness will occur at some time in the future, quicker for some than others. There are nerve endings that may become involved with healing scars from surgery such as suction-assisted lipectomy, abdominoplasty, facelifts, body lifts, and extremity surgery. While there may not be a major nerve injury, the small nerve endings during the healing period may become too active and produce a painful or oversensitive area due to the small

sensory nerve involved with scar tissue. Often, massage and early nonsurgical intervention resolves this. It is important to discuss postsurgical pain with your surgeon.

Bleeding:
It is possible, though unusual, to experience a bleeding episode during or after surgery. If postoperative bleeding occurs, it may require emergency treatment to drain accumulated blood or you may require a blood transfusion, though such occurrences are rare. The collection of blood that can occur under your skin following surgery is referred to as a hematoma. Increased activity too soon after surgery can lead to an increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time. Nonprescription "herbs" and dietary supplements can increase the risk of surgical bleeding. A hematoma can occur at any time, usually in the first three weeks following injury to the operative area. If blood transfusions are necessary to treat blood loss, there is a risk of blood-related infections such as hepatitis and HIV. Your surgeon may provide medications after your surgery to prevent blood clots. Medications that are used to prevent blood clots in veins can produce bleeding and decrease blood platelets.

Infection:
Infection, although uncommon, can occur after surgery. If an infection occurs, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary. It is important to tell your surgeon of any other infections, such as a history of methicillin-resistant Staphylococcus aureus (MRSA) infections, an open wound, recent upper respiratory infection/pneumonia, ingrown toenail, insect bite, tooth abscess, or urinary tract infection. Infections in other parts of the body may lead to an infection in the operated area. Postoperative infections often result in more extensive scarring and predispose the patient to revision surgery.

Ileus:
The return of bowel function following surgery is important. An ileus is a disruption in bowel function caused by the failure of peristalsis or by hypomobility of your bowels/gut resulting in a lack of defecation and possibly repeated vomiting. Anesthetics and medications like pain medications given to you at the time of surgery can contribute to the development of an ileus in the postoperative period. An ileus can result in abdominal distention, vomiting, inability to absorb oral medications, and possibly hospitalization. Repeated vomiting could result in aspiration pneumonia and respiratory failure. It is essential to have regular bowel function after your surgery.

Scarring:
All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, this surgery will result in long, prominent scars that are permanent. Abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There is a possibility of visible marks in the skin from sutures. These scars may become raised, red, or discolored in the first few weeks/months, but usually settle down over time. However, some patients are prone to "hypertrophic" or "keloid" scars, which are prominent, raised, red scars that do not settle. Further treatments with medications and/or surgery may be required.

Firmness:
Excessive firmness can occur after surgery due to internal scarring. The occurrence of this is not predictable. Additional treatment including surgery may be necessary.

Skin Sensitivity:
Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. This usually resolves during healing, but in rare situations, it may be chronic.

Major Wound Separation:
Wounds may separate after surgery. If this occurs, additional treatment including surgery may be necessary.

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 suture removal.

Damage to Deeper Structures:
There is a potential for injury to deeper structures including nerves, blood vessels, lymphatics, muscles, and lungs (pneumothorax) during any surgical procedure. The potential for this to occur varies according to the type of procedure being performed. Injury to deeper structures may be temporary or permanent.

Fat Necrosis:
Fatty tissue found deep in the skin might die. This may produce areas of firmness within the skin. Additional surgery to remove areas of fat necrosis may be necessary. There is a possibility of contour irregularities in the skin that may result from fat necrosis.

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

Shock:
In rare circumstances, a 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.

Pain:
You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after surgery. If you are a chronic pain patient followed by a pain therapy practitioner, you may be asked to see this practitioner preoperatively to assist you in the management of your pain disorder in the postoperative period. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

There are nerve endings that may become involved with healing scars from surgery. While there may not be a major nerve injury, the small nerve endings during the healing period may become too active and produce a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often, massage and early nonsurgical intervention resolves this. It is important to discuss postsurgical pain with your surgeon.

Cardiac and Pulmonary Complications:
Pulmonary complications may occur secondarily to blood clots (pulmonary emboli), fat deposits (fat emboli), pneumonia, 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 swelling in your legs or blood clots 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 heartbeats, seek medical attention immediately. If any of these complications occur, you may require hospitalization and additional treatment.

Venous Thrombosis (Clot) and Sequelae:
Thrombosed veins, which resemble cords, occasionally develop in the area of the breast or around IV sites, and usually resolve without medical or surgical treatment. It is important to discuss with your surgeon any birth control pills you are taking. Certain high estrogen pills may increase your risk of thrombosed veins. Personal history of bleeding and clotting problems may also increase your risk of thrombosed veins.

Allergic Reactions:
In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations, or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur in response to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment. It is important to notify your physician of any previous allergic reactions.

Drug Reactions:
Unexpected drug allergies, lack of proper response to medication, or illness caused by the prescribed drug are possibilities. It is important for you to inform your physician of any problems you have had with any medication or allergies to medication, prescribed or over the counter, as well as medications you regularly take. Provide your surgeon with a list of medications and supplements you are currently taking.

Surgical Wetting Solutions:
There is a possibility that large volumes of fluid containing dilute local anesthetic drugs and epinephrine that is injected into fatty deposits during surgery may contribute to fluid overload or systemic reaction to these medications. Additional treatment including hospitalization may be necessary.

Fat/Air Embolism:
In rare cases, fat particles or air can enter the vascular system and can travel to the heart, lungs, or brain. This can result in significant complications including death.

Persistent Swelling (Lymphedema):
Persistent swelling can occur following surgery.

Unsatisfactory Result:
Although good results are expected, there is no guarantee or warranty, expressed or implied, on the results that may be obtained. The body is not symmetric and almost everyone has some degree of unevenness that may not be recognized in advance. One side of the face may be slightly larger or droopier. The breast and trunk areas exhibit the same possibilities. Many of such issues cannot be fully corrected with surgery. The more realistic your expectations as to results, the better your results will appear to you. Some patients never achieve their desired goals or results, at no fault of the surgeon or surgery. You may be disappointed with the results of surgery. Asymmetry, unanticipated shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Size may be incorrect. Unsatisfactory surgical scar location or appearance may occur. It may be necessary to perform additional surgery to improve your results. Unsatisfactory results may NOT improve with each additional treatment.

ADDITIONAL ADVISORIES

Medications and Herbal Dietary Supplements:
There are potential adverse reactions that occur as a result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with forming blood clots, and therefore may contribute to more bleeding issues. If you have a medical condition (such as heart arrhythmia, heart stent, blood vessels with blockages, or blood clots) and are taking medications to thin your blood and prevent clotting such as Plavix®, Coumadin®, Xarelto®, Effient®, or Pradaxa®, you should discuss management of these medications around the time of surgery with your plastic surgeon. Your plastic surgeon may coordinate a plan for these medications with the doctor that prescribed them for your medical condition. If you have been prescribed drugs for a medical condition, do not stop them without discussing it first with your plastic surgeon. Stopping these medications abruptly may result in a heart attack, stroke, or death. Be sure to check with your physician about any drug interactions that may exist with medications that 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, know 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.

Sun Exposure – Direct or Tanning Salon:
The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their surgeon and either delay treatment, or avoid tanning until the surgeon says it is safe to resume. The damaging effect of sun exposure occurs even with the use of sunblock or clothing coverage.

Travel Plans:
Any surgery holds the risk of complications that may delay healing and your return to normal life. Please let the surgeon know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame. Allow at least 10-14 days before travelling via air. Medications may be required if you have a long flight/trip to prevent deep vein thrombosis (DVT)/pulmonary embolism (PE) in the immediate postoperative period.

Long-Term Results:
Subsequent alterations in the appearance of your body may occur as a result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause, or other circumstances not related to your surgery.

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.

Body Piercing:
Individuals who currently wear body-piercing jewelry in the surgical region are advised that an infection could develop from this activity. Body-piercing jewelry should be removed prior to your surgical procedure.

Nails:
To determine your vital status during surgery your anesthesia provider may require access to your fingernails for monitoring. Make sure to have at least two fingernails free of nail polish or acrylic nails on the date of your surgery.

Jewelry:
Jewelry should not be brought with you at the time of your surgical procedure. Items such as earrings, wedding rings, and necklaces should be removed and placed in a safe place.

Future Pregnancy and Breastfeeding:
This surgery is not known to interfere with pregnancy. If you are planning a pregnancy, your breast skin may stretch and offset the results of surgery. You may have more difficulty breastfeeding after this operation.

Female Patient Information:
It is important to inform your plastic surgeon if you use birth control pills or 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 coagulation of blood vessels and increased activity of any kind may open these vessels leading to a bleed or hematoma. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery to control bleeding. It is wise to refrain from intimate physical activities until your physician states it is safe.

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 are often 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 (Reoperations)
There are many variable conditions that may influence the long-term result of surgery. It is unknown how your tissue may respond or how wound healing will occur after surgery. Secondary surgery may be necessary to perform additional tightening or repositioning of body structures. If complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are associated with this surgery. Other complications and risks can occur but are less common. 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. You and your surgeon will discuss the options available if additional surgery is advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, and pathology and lab testing fees.

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 postoperative 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 important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

ATTESTATIONS

Smoking, Secondhand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray):
Patients who are currently smoking or use tobacco or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin loss, delayed healing, and additional scarring. Individuals exposed to secondhand 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 these types of complications. Please indicate your current status regarding these items below**:**

__ I am a nonsmoker and do not use nicotine products. I understand the potential risk of secondhand 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.

__ I have smoked and stopped approximately _____ ago. I understand I may still have the effects and therefore risks from smoking in my system if not enough time has lapsed.

___ I have been advised to stop smoking immediately and have been informed of the risks, benefits, expectations, and alternatives to my surgery if I continue smoking.

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. I acknowledge that I will inform my physician if I continue to smoke within this time frame, and understand that for my safety, the surgery, if possible, may be delayed.

Smoking may have such a negative effect on your surgery that a urine or blood test just before surgery may be done that will prove the presence of nicotine. If positive, your surgery may be cancelled and your surgery, scheduling fee, and other prepaid amounts may be forfeited. Honestly disclose smoking to your surgeon.

Sleep Apnea/CPAP:

Individuals who have breathing disorders such as obstructive sleep apnea and who may rely upon continuous positive airway pressure (CPAP) devices or utilize nighttime oxygen are advised that they are at a substantive risk for respiratory arrest and death when they take narcotic pain medications following surgery. This is an important consideration when evaluating the safety of surgical procedures in terms of very serious complications, including death, that relate to preexisting medical conditions. Surgery may be considered only with monitoring afterwards in a hospital setting to reduce risk of potential respiratory complications and to manage pain safely following surgery.

Please consider the following symptoms of sleep apnea:

I am frequently tired upon waking and throughout the day

I have trouble staying asleep at night

I have been told that I snore or stop breathing during sleep

I wake up throughout the night or constantly turn from side to side

I have been told that my legs or arms jerk while I am sleeping

I make abrupt snorting noises during sleep

I feel tired or fall asleep during the day

It is important for you to inform and discuss any of the above symptoms that you have experienced with your surgeon.

It is important for you to inform and discuss any of the above symptoms that you have experienced with your surgeon.

DVT/PE Risks and Advisory:

There is a risk of blood clots, deep vein thrombosis (DVT), and pulmonary embolus (PE) with every surgical procedure. It varies with the risk factors listed below. The higher the number of risk factors, the greater the risk and the more involved you must be in both understanding these risks and, when permitted by your physician, walking and moving your legs. There may also be leg stockings, squeezing active leg devices, and possibly medicines to help lower your risk.

There are many conditions that may increase or affect risks of clotting. Inform your doctor about any past or present history of any of the following:

Past history of blood clots
Family history of blood clots
Birth control pills
Hormone stimulating drugs
Swollen legs
History of cancer
Large dose of vitamins
Varicose veins
Past illnesses of the heart, liver, lung, or gastrointestinal tract
History of multiple spontaneous abortions or miscarriages

_____I understand the risks relating to DVT/PE and how important it is to comply with therapy as discussed with my surgeon. The methods of preventative therapy include:

Early ambulation when allowed

Compression devices (SCD/ICD)

Anticoagulation protocols when allowed

For high-risk patients, the risks of VTE are still high, even in the setting of appropriate chemoprophylaxis. If your surgery is elective and you are a high-risk patient, it is best to consider with not proceeding with the elective surgery.

COMMUNICATION ACKNOWLEDGEMENT – CONSENT

There are many ways to communicate with you. It is important to keep appointments and let us know if problems or issues arise. Methods of communicating are by telephone, text, pager, answering service if available, email, and regular mail. If an emergency arises, keep us alerted to your progress so we may aid in any necessary treatments. Please do not leave a message after hours or on weekends on the office answering machine if any urgent or emergent situation exists, as there is a delay in retrieving such messages. All attempts will be made to preserve your privacy in accordance with HIPAA rules.

Please confirm below all acceptable ways of communicating with you:

____ Telephone
____ Home (- -)
____ Work (- -)
____ Cell (- -)
____ Text
____ Pager – answering service if available
____ Email – with up-to-date email address (@)
____ Regular mail and delivery

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.

CONSENT for SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr. Samer Cabbabe and such assistants as may be selected to perform **Breast Reconstruction with Tissue Expander/Implants Surgery**.

   I have received the following information sheet: **Breast Reconstruction with Tissue Expanders/Implants/Fat/Latissimus Dorsi/Mesh/Acellular Dermis**

2. I recognize that during the course of the operation 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 their 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 understand what my surgeon can and cannot do, and understand there are no warranties or guarantees, implied or specific, about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

5. I consent to be photographed or televised before, during, and after 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 that may be removed.

8. I am aware that there are potential significant risks to my health with the utilization of blood products, and I consent to their utilization should they be deemed necessary by my surgeon and/or his/her appointees.

9. I authorize the release of my Social Security Number to appropriate agencies for legal reporting and medical device registration, if applicable.

10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.

11. I realize that not having the operation is an option. I opt out of having this procedure _____.

12. 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

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12).
I AM SATISFIED WITH THE EXPLANATION.

_____

Patient Name (please print): Patient Signature:

Date/Time _____

ASPS Member Surgeon®

Informed Consent Form- "Off-Label" Use of Acellular Dermal Matrices (ADMs)

INSTRUCTIONS

This document is about informed consent. It will tell you about the off-label use of acellular dermal matrices (ADMs) for breast reconstruction and other breast surgeries.

It is important that you read this whole document carefully. Signing the consent agreement means that you agree to the surgery that you have talked about with your plastic surgeon.

GENERAL INFORMATION

The Food and Drug Administration (FDA) requires medical devices in the United States to be safe and work well. Each device's label and advertising say that the device may be used in ways that are "approved" by the FDA.

An "off-label" use of a device means that it is not listed as an "approved" use on the label. The FDA does not approve of this. However, doctors may use a device in a way that is not listed on the "approved" label. They can do so based on everything they know and have worked with. They can also do so if the use is reasonable and helpful.

ADMs FOR BREAST RECONSTRUCTION OR OTHER BREAST SURGERIES

Your surgeon needs to put an implant in the right position and keep it there. Your surgeon may use biological materials called ADMs for this. Often, these materials are made from human or pig skin. These materials are processed and do not have living cells. Your own cells will grow into the ADM. The tissue will become like your own. These products may release fluid. They may need drains for a few days or weeks.

The FDA has not approved ADMs for breast reconstruction or other breast surgeries. That said, ADMs have FDA approval for certain uses, like soft tissue coverage. That allows surgeons to use ADMs in an "off-label" way. For instance, in breast reconstruction or another breast surgery.

CONSENT FOR SURGERY/PROCEDURE

1. I understand that using ADMs in breast reconstruction and other breast surgeries is "off- label" and not approved. ADMs have FDA approval for certain uses.
2. I understand how this treatment has been explained. I understand the benefits, risks, and disadvantages.
3. Other treatments, prescriptions, and therapies have been explained. I understand their benefits, risks, and disadvantages.
4. I agree that the risks and complications of off-label use of ADMs have been explained to me. They may include:
   - Fluid buildup under the skin (seroma). It may require drains for a long time
   - Breast infection
   - Slow healing or opening of the cut (wound dehiscence)
   - Bleeding (hematoma)
   - A breast implant or tissue expander may become exposed. It would need to be removed
   - The skin on the breast could die (skin necrosis)
   - Capsular contraction could happen again
   - The implant could move around in the breast
   - ADM may not become part of my own tissue. It would need to be removed
5. I have told the doctor about all my allergies.
6. I have told the doctor about all the medications I am currently taking, like my prescriptions, over-the-counter drugs, herbal supplements, aspirin, and any non- prescription drug or alcohol use.

7. My doctor has told me whether I should stop taking any medications after getting the ADMs with breast reconstruction and other breast surgeries.
8. I am aware and accept that there are no guarantees for the results of the ADMs in my breast reconstruction and other breast surgeries.
9. The doctor has answered all my questions about ADMs in breast reconstruction and other breast surgeries.

With my signature, I certify that I have read and understood this document and that I agree to it. I permit Dr. Cabbabe to prescribe the use of ADMs for breast surgery which is an "off-label" and non-approved use of ADMs.

I CONSENT TO THE PROCEDURE OR TREATMENT AND THE ITEMS LISTED ABOVE (1-9). I UNDERSTAND THE EXPLANATION AND HAVE NO MORE QUESTIONS.

_____ _____

Patient Name (please print) Patient Signature:

_____

Date/Time

I, _____, have discussed with Dr. Samer/ Edmond Cabbabe and fully understand and accept the following with regard to my desire for breast augmentation using an implant, which may potentially be larger than optimal for my breast tissue and body proportions.

I acknowledge that I fully understand each item listed below.

I have had an opportunity to have all my questions answered, and I feel informed and accept each risk or tradeoff listed below as indicated by my initial(s) _____ beside each item. **(Please place your initials in the blank at left, and then initial each box beside each item below).**

___ As I get older, my breast skin will age, stretch, and become thinner even without an implant. The larger any breast, augmented or not, the worse it will look over time due to skin stretching.

___ Adding any implant to my breast adds weight and will result in the stretching and irreversible thinning of my breast tissues over time.

___ The larger the implant, the greater the amount of breast tissue stretching that will occur.

___ Adding excess weight to the breast almost guarantees that it will look worse over time, with increased stretch and sagging. It is impossible to predict whether or when this will occur in any individual patient.

___ Adding weight to my breast with a large implant may cause me to need further surgery in the future, particularly mastopexy (breast lift) with additional visible scars and risks. I will incur additional costs, time off from work, risks, and tradeoffs if additional surgery is necessary.

___ Excessive breast tissue stretch from a large implant can make me more likely to have surgical complications with healing problems if the tissues become very thin.

___ As breast tissues thin, I will definitely be able to feel my implant, portions of the implant may be visible through my skin, and visible rippling or wrinkling may occur.

___If excessive stretching or complications occur (this is unpredictable), it may even become necessary to remove the implants, which may compromise the appearance of my breasts and lead to visible scarring if breast lifting (mastopexy) is necessary following implant removal.

___When I request implants larger than Dr. Samer Cabbabe feels are optimal for my tissues and body proportions, I am overruling Dr. Samer Cabbabe's years of experience and judgment, and I accept full responsibility for every possible outcome of my decision, whether that outcome or risk is known or unknown to me and to Dr. Samer Cabbabe.

___I understand and accept all of these risks, limitations, and tradeoffs, and request that Dr. Samer Cabbabe proceed with the larger than optimal implant augmentation of my breasts. I have had an opportunity to have all of my questions answered to my satisfaction and am totally comfortable with my decision.

Signed this _____day of the month of _____, 20_____ at _____ AM/PM.

_____ _____

Patient: (Please print) Patient Signature

CONSENT TO USE OF MESH FOR SUPPORT IN THE BREAST

Use of P4HB Natural Scaffold (Galaflex) or OTHER BREAST MESH:

In some cases, Dr. Cabbabe recommends using a soft tissue support natural scaffold called Galaflex (poly-4 hydroxybutyrate (P4HB)). This scaffold adds support to the healing tissues. P4HB is FDA approved for soft reinforcement in plastic and reconstructive surgery procedures. P4HB does not have a specific "breast use label" indication, but breast lifts, breast augmentation and breast revisions are plastic and reconstructive procedures.

The mesh may be placed in an attempt to support the breast implant or breast tissue. The implant may remain supported, but the breast tissue frequently does not maintain the same support, which can lead to breast tissue sagging on top of the implant. This can be noticeable within months after surgery and the aging process continues over time. This occurs because of the inherent tissue qualities of your breast and is not a result of the surgeon not removing enough tissue. Patients with weight loss, pregnancy or other inelasticity of the breast are the most frequently affected.

Every patient has inherent breast asymmetries, many of which are not correctable. The mesh could be placed too tight which could lead to one or both implants sitting too high, particularly in the case of poor overlying skin/tissue qualities. Asymmetries can occur for this reason also. Breast implant capsular contracture can also lead to asymmetries and need for revisions.

Breast lift with implant surgery carries over a 25% revision rate. Patients with "stretchy" tissues or thicker breasts carry higher rates of revision and may need secondary breast lifts. Galaflex, or any other breast mesh that is used, may be felt (palpable) through thin breast tissue, or can create visible distortions. Mesh can become infected, or exposed, and may need to be removed and then later replaced.

_____ _____

Patient Name (please print) Patient Signature:

_____

Date