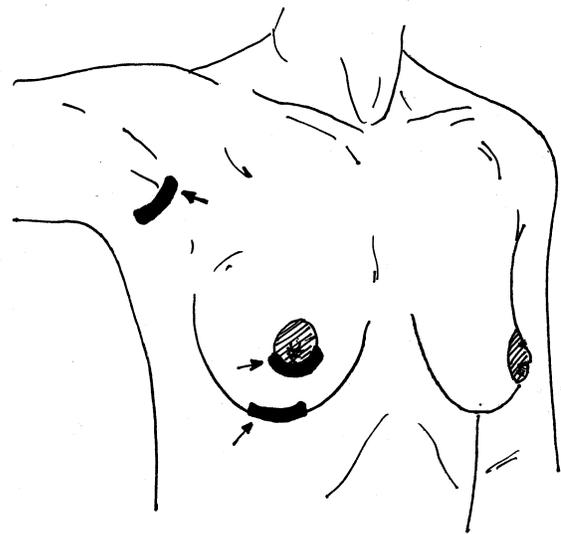


BREAST AUGMENTATION

Breast augmentation is an elective operation aimed at increasing the size of the breast. It may also help create symmetry where there may be a size discrepancy between the two breasts. It will not necessarily remedy the problems related to excess skin and a droopy breast may not be elevated to an acceptable degree. If this is your concern or if it is deemed that an implant will not eliminate the excess skin problem then an additional operation called a Mastopexy (breast lift) may be indicated. The goals of breast augmentation are to create a larger, more proportional breast which maintains normal softness or sensitivity and function. The operation cannot create younger skin nor eliminate stretch marks. It cannot eliminate asymmetry such as large differences in breast shape or position, rib cage irregularities or nipple/areola size discrepancy. If these are concerns please bring these up for discussion. Additional operations may be required and/or your goals may be only partially met.

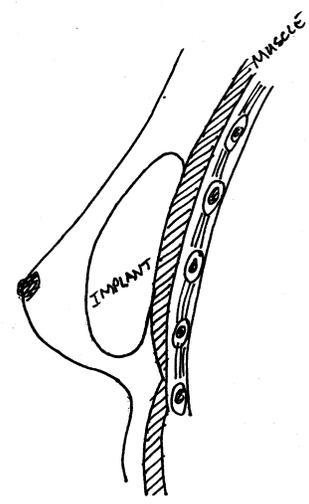
The operation will require a scar and this can be in one of three locations. It could be a scar within the axilla (armpit), one around the lower portion of the areola or one beneath the breast. Each of these incisions and resultant scars have their advantages and disadvantages. Scars beneath the arm may be unsightly and be unable to be covered by swim wear or sleeveless evening wear. Also, dissection from this position is done without direct observation and increased incidence of bleeding, contour irregularities or migration of the implant towards the axilla may be experienced. Complications may be unable to be addressed through this scar and there is a higher incidence of needing a separate incision (and resultant scar) if this approach is chosen initially. The incision around the areola usually is from the 3 to 9 o'clock position around the bottom of the nipple. This approach has a well concealed scar as it is normally at the junction of the lighter pigmented breast skin and the darker pigmented areola. Difficulty with insertion of the implant may result with this approach. This is related to the smaller size of the incision in relation to the size of the implant. It also requires more dissection around the lower portion of the breast gland which may cause some puckering, more wrinkling and distortion as well as prolonged healing in initial recovery. Difficulty of insertion of a textured implant is also possible and if a textured implant is chosen with this incision a smaller implant may be necessary. Due to distortion, increased resistance of insertion of the implant through this approach increases risk of implant rupture or distortion (This also applies to an approach through the axilla).



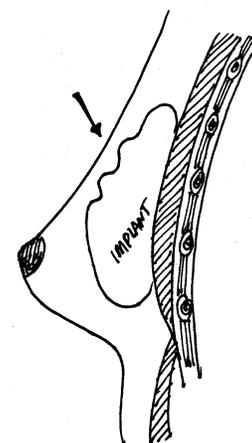
Michael D Manuel, M.D.
Plastic and Reconstructive Surgery

The incision on the undersurface of the breast is usually 1/2 to 1 inch above the crease depending on breast size. It is generally 1 to 1 1/2 inches in length. Incision length is primarily related to incision location and implant size. The scar may show hypertrophy manifested by redness, irritation, widening and thickening of the scar. This is usually temporary and the scars in general are quite acceptable. It may take several months to one year for the scar to fully mature and become less noticeable, however, it will always be a visible scar. Revision of the scar is a possibility following complete maturation if the scar still is unacceptable.

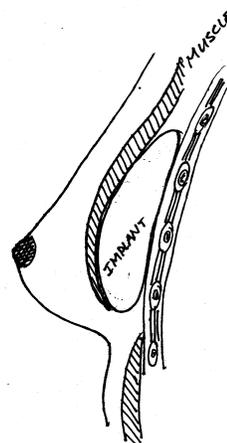
Following the incision a pocket is made for the implant. This pocket is made larger than the implant so that the implant will move naturally. It should settle within the lower part of the breast when sitting or standing and have enough movement that it appears and feels like normal breast tissue. This pocket can be placed in one of two locations as indicated in the brochures that you have been given. The first is in a position immediately beneath the breast gland and above the muscle, as depicted on this page. The advantages of this operation include shorter recovery time, shorter operation time and the ability to be done under local anesthesia. The disadvantages of this procedure are primarily that of the superficial nature of the implant. This may result in an implant whose edges are able to be seen or felt if there is inadequate fat or breast tissue overlying the implant. The second possible position for the pocket is beneath not only the breast gland but also behind the pectoralis or chest wall muscle. This is a position between the major chest wall muscle and the underlying muscles and rib. During this procedure a small portion (less than 10%) of the attachment of this muscle is loosened to allow more natural implant positioning. The advantages of this operation include being deeper within the body which adds an additional layer of covering over the implant. This has two beneficial effects. The first is to lessen the likelihood of being able to see or feel the edges of the implant. This tends to give a more natural breast appearance especially in the upper aspect of the breast. There have been some instances of some downward displacement with time and this is thought due to the muscular activity of the implant. The second advantage of being behind the muscle is related to breast softness. It is well documented that submuscular position of the implant gives a softer more natural feeling breast. This is regardless of type of implant used. This may be a protective effect of the muscle or may be due to the continual massage with normal arm activity.



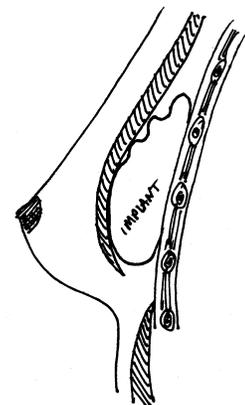
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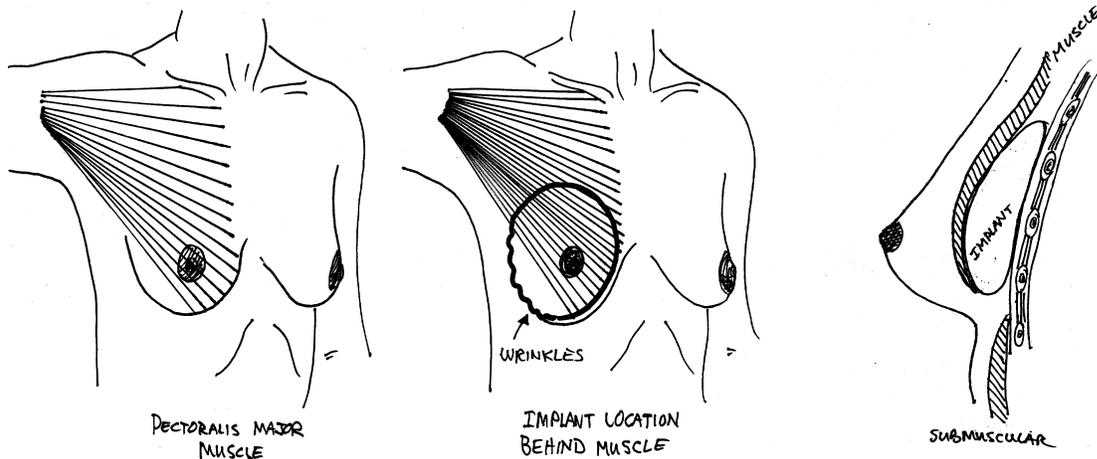
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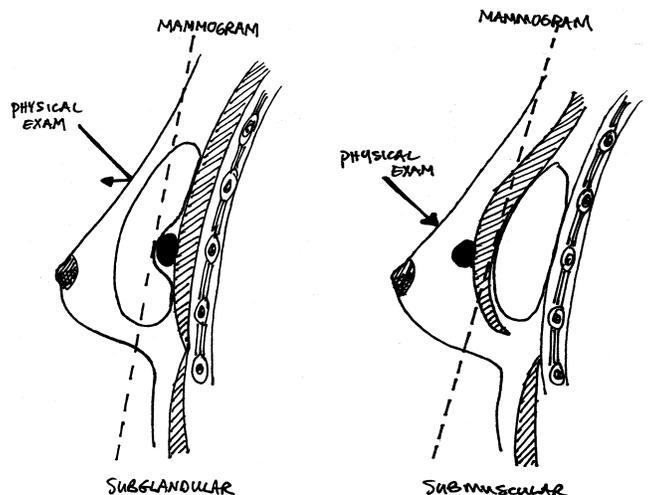
SUBMUSCULAR



SUBMUSCULAR



As will be discussed later, although the implants do not cause cancer there is a potential for the implants to interfere with early detection of breast cancer. This may be accentuated by the placement of the breast implant immediately behind the breast gland. During that operation there is a potential for residual breast tissue to be left between the implant and the underlying muscle. This breast tissue has a theoretical possibility of developing a cancer which would be hidden both to physical exam and mammographic examination by normal means. This would result in a cancer which may be detected late and have a worse prognosis. Placement of the implant behind the muscle leaves this breast tissue unaltered and in its normal position in front of the muscle. This leads to easier examination of the entire breast by both physical and radiographic means. It is for this reason that I recommend submuscular placement in the majority of women.



The incision (regardless of location) and subsequent dissection for formation of the pocket may interfere with nerve supply to the nipple. These nerves are small and usually not directly visualized. Irritation of the nerve, bruising or perhaps even direct cutting of the nerve may be unavoidable at the time of surgery. This may result in a slight decrease in nipple sensation or may result in total absence of feeling in the nipple or areola. Increase in sensation to a disagreeable level may also be possible. There is always some temporary loss which should return in 3 to 4 months. However as mentioned these changes may be permanent and for the large part irreversible. Similar changes within the skin in various portions of the breast may also lose or gain sensitivity which may be permanent and irreversible. Return of sensation varies among patients and has taken as long as several years for sensation to return in a few instances. Feeling of cold may also be accentuated following this procedure. This procedure may also interfere with the ability to breast feed with the dissection near the breast gland. This may range from decreased volume of breast feeding to total inability to lactate. Once again this may be permanent and irreversible.

Other potential complications related directly to the surgery include asymmetry (difference in breast size and shape). Asymmetry may be attributable to either preexisting anatomic asymmetry, incorrect choice of implant size, contracture of the fibrous capsule, collections of blood or serum, discrepancy in muscle development between the sides or rupture of the implant. Pre-existing asymmetry MAY possibly be corrected at the time of the initial procedure. Pre-existing asymmetry may be actually accentuated with placement of the implant and enlarging of the breast.

Continued sagging of the breast is inevitable due to the effects of gravity and decrease in elasticity of the skin.

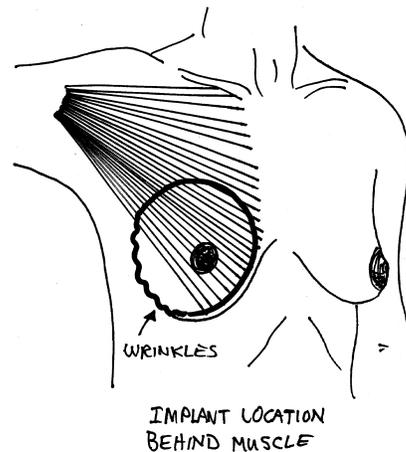
Breast pain of various intensity and duration has been reported as an expected occurrence following breast implant surgery. In addition, an excessive capsular contracture can cause generalized or localized breast pain.

Complications of bleeding, infection, fluid accumulation, too tight of closure or too large an implant may result in delayed wound healing. Pre-existing conditions in the area including burned or scarred skin overlying the incision may also inhibit wound healing. Exposure or extrusion of the implant may occur. **Smoking will increase your risk of healing complications.** Skin breakdown may be attributed to inadequate circulation due to discrepancies in either the skin thickness or implant size. It may be also directly related to post operative trauma to the skin. Implant exposure or removal may result. These chances are lessened when the implant is placed beneath the muscle.

More common but still rare potential wound problems are related to bleeding and infection. Bleeding is rare after a three week period however, during this time one is encouraged to keep the arm activity to a minimum and not participate in any athletic or other strenuous activities. Normal motion for hygiene and hair washing is permitted. If bleeding does occur it will require a second, urgent operation for removal of the implant, evacuation of the blood and finding the bleeding source. The implant can usually be replaced at the time of this procedure and the final results are usually unaffected. Minor amounts of bleeding which may go on undetected may proceed to form fibrous scar contracture. Infection may require removal of the implant for treatment. This may result in a period (several months to a year) without the implant on that side to allow the infection to resolve. Usually surgical replacement of the implant can be done at a later date following resolution of the infection and softening of the resultant tissues. The end result following infection and implant replacement is usually not as pleasing and there may be significant asymmetry. Either bleeding or infection may result in additional hospitalization and/or time off work. These may result in additional costs which may not be covered by your insurance.

Shifting of the implant within the pocket may lead to asymmetry or distortion of breast shape. This is more common with the textured implants, however, may also result with the smooth walled implants. This may result from inadequate scar formation and inability of the tissues to hold the implant in place. This, combined with the effects of gravity may lead to settling or shifting of the breasts in a more downward or outward position. Re-operation may be the result.

Wrinkles or folds in the implant shell may occur and be visible or able to be felt beneath the overlying tissue. These conditions are increased in frequency if you are thin, small framed or there is a small amount of overlying breast tissue. Large implants or the formation of scar tissue (capsular contracture) may also distort the implant and cause folds or wrinkling. The placement of the implant beneath the muscle lessens the likelihood of these being felt however they may still exist in the lower portions of the breast. Surgical revision may be desired by some patients exhibiting folds or wrinkles, however some times this is ineffective. For some patients these features diminish with time however reports of folds leading to thinning or erosion of the overlying tissue and subsequent implant exposure and removal do exist. Breast self-examination is important so that you may learn to differentiate implant folding from abnormal breast tissue.



Calcification in the tissue surrounding the implant may also result from the operation. It is not known whether this is due directly to the operation itself or the effects of the implant. It is probably a combination of both factors. Calcification around the implant may lead to a hardened, distorted breast or may interfere with mammography in the early detection of cancer.

The implant for breast augmentation is a foreign object. Each patient's tolerance to surgery, medication, implantation with a foreign object may be different. There are currently multiple types of implants available for implantation. The standard implant consists of a silastic (silicone rubber) outer envelope which is filled with saline, commonly known as salt water. This is also known as an "Inflatable Implant." Silicone gel implants, although still available for some applications, are not available to new patients seeking augmentation. Various forms of these implants have been available for approximately 30 years.

The outer surface of the implant can vary. The outer shell can either be smooth or it can be textured. The smooth walled implants were the first to be developed and again have been used in various forms for approximately 30 years. The textured implant coating was developed to attempt to decrease the degree of scar hardening around the implant. In the subglandular position this has helped but in the submuscular position there is no benefit.

Each implant has its advantages and disadvantages. Many surgical choices exist and most surgeons take into account the current implant technology and their own training and experience with these implants to advise as to implant choice.

The inflatable implant (saline filled) again has advantages and disadvantages. The advantage of having saline rather than silicone fill is that should rupture occur the saline will be rapidly absorbed by the body. Saline is a substance found naturally within the body and causes no reaction. It is the same solution given through the IV at the time of surgery. The major disadvantage with inflatable implants is the possibility of spontaneous deflation. This deflation can occur from ruptures along the edge or from the filling valve itself. Should this occur, rapid deflation and loss of volume results. This would require a second operation for implant replacement. Depending on the incision location (beneath the breast), replacement can be done in the office under local anesthesia and requires only a short recovery period. The implant manufacturer warrants the implant so that you can obtain a new one at **no** additional cost.

Because of the foreign body characteristics of the implant there are several concerns directly related to the presence or consistency of this foreign body. The first is a natural tendency of any foreign implanted object to form scar tissue around it. This is true of a pacemaker, artificial knee or breast prosthesis. The unique thing about a breast prosthesis is that it is compressible and the others are firm. This compressibility is desirable in that it mimics the natural appearance and feel of breast tissue. **ALL PATIENTS FORM CAPSULES OF SCAR AROUND THEIR IMPLANTS.** However, each patient's capsule will vary in degree ranging from thin to heavily thickened. Contracture of a fibrous capsule may occur independent of its thickness resulting in discomfort, pain, excessive breast firmness, an implant which can be felt and/or may recreate wrinkles or folds in the prostheses' outer shell. It may also create displacement of the prosthesis. The presence and degree of **capsular contracture** may affect the diagnostic value of mammographic procedures as will be discussed later. Although the cause of capsular contracture is not known, several reports have implicated low-grade infection, blood collection, implant volume, patient's own immune system, implant type, trauma and foreign body reaction as possible etiologies. There is no one common factor present in patients who develop hardening of their breasts. It more commonly occurs on one side than on both sides which further complicates the implication of one single factor. With submuscular placement of the implants, approximately 10 to 15% of patients will develop some unnatural firmness. Of these, approximately 1/3 (5% of total) will desire some treatment. As mentioned this treatment is currently surgical in nature. It usually consists of reoperation through the initial incision with removal of the implant, cutting the scar tissue and replacement of the implant. If your implant is not in the submuscular position it may be moved to that position to lessen the likelihood of recurrence of the hardness. Attempts have been made in the past to apply external pressure (closed capsulotomy) to break up the scar tissue. This has resulted in several instances of implant rupture. The chance of excessive capsular contracture for all patients with implants will increase in time and may necessitate reoperation. Occasionally there will be an underformation of this scar tissue which may result in migration or increased movement of the implant. This malpositioning is most commonly appreciated when lying on one's back when the breasts settle to the side. Treatment for this malposition may require a tightening of the scar capsule or placement of a larger implant.

Either over or under production of the scar tissue may result in the need for additional surgical correction and this may result in additional time off work or additional expense and discomfort. Despite surgical correction of the over or under production of scar tissue, recurrence of either condition may be inevitable and additional surgeries may be required.

Another concern regarding any foreign body in particular the breast region is that of breast cancer. Breast cancer is one of the most common malignancies affecting humans and affects approximately one out of every nine women in the United States. As there are currently over 2 million women with breast implants in place, the groups of women who have implants and the groups of women who develop breast cancer are going to overlap. Initial studies in the placement of implants in rodents reveal that there is a tumor called sarcoma which developed in these rats. These sarcomas are in no way related to human breast cancer and are a completely different form of tumor. In addition these rodents formed these sarcomas to all implanted materials that have smooth walls regardless of internal makeup. This includes various metals, various plastics and glass. *In regards to human breast cancer, there has been at no time during the past 35 years of implant use, any indication of breast cancer occurring in greater frequency in women with breast implants.* In a large national study involving over 3000 women who have had their implants in place an average of 11 years, the incidence of breast cancer in augmentation patients has been shown to be no greater than in women who do not have implants. That finding holds true for women in the study population who have had their implants in place for more than 20 years. At this time it is thought that breast implantation does *not* cause breast cancer.

In regards to breast cancer there is another issue, that being interference with early tumor detection. The presence of an implant does indeed make it more difficult to thoroughly exam a breast using mammography or by physical examination. This is especially true when the implant is positioned just beneath the breast gland or if there is severe contracture and hardness around the breast implant. Any woman considering breast augmentation should take this into consideration. In particular, those women who may have a personal history of breast cancer or other significant risk factors including family history of breast cancer should carefully consider alternative treatments. Although it has been documented that some breast tissue may be masked by the presence of implants an actual case of late cancer detection due solely to the implants is a rare occurrence.

Evidence indicates that if the proper exams (using special techniques) are performed at the appropriate intervals, cancer diagnosis should not be delayed. Physical self-examination of the breast should be carried out at least monthly following the operation to become acquainted with the new breast size and characteristics. Annual physical examination by a practitioner experienced in examination of women with breast augmentation should also be performed. The above mentioned fold or wrinkles may mimic breast masses and may be subject to biopsy if detected by a physician with less experience in palpation of the augmented breast. This does not mean that all masses within the breast are related directly to the implant and any suspicious masses found by examination should be evaluated and biopsied if deemed necessary. **BREAST IMPLANTS DO NOT CAUSE CANCER BUT BREAST CANCER CAN OCCUR IN AN AUGMENTED BREAST.**

The radiographic or mammographic evaluation of the breast must also be considered in a different light when dealing with presence of breast implants. This type of exam is more difficult in augmented breasts because the silicone rubber outer shell is opaque to X-rays and because the implants compress breast tissue. However, most radiologist experienced with this type of exam agree that when extra customized X-rays are taken, mammography of augmented breasts can be almost as thorough as in women who have not had their breasts enlarged. In some women, especially those with a significant capsular contracture, portions of breast tissue may be hidden from view despite the most diligent diagnostic techniques. To date there are few if any published reports documenting a case in which a breast implant caused cancer to be hidden. However there is at least a theoretical risk of delay in diagnosis. Postoperatively it is recommended that a mammogram be obtained approximately 12 to 18 months following the operation and this will become a new baseline for comparison for future tests. Following the operation I recommend a mammogram every 1 to 2 years between the ages of 35 and 50 and annually after the age of 50. Women who have significant risk factors for breast cancer such as personal or close family history of the disease should consider whether they want to expose themselves to the theoretical possibility of delayed detection. If surgery is elected, the frequency and type of mammogram performed should be customized according to the woman's individual needs. These additional X-rays as well as a more complicated technique for thorough visualization may result in increased cost of the mammographic procedure. There is a slight but possible risk of implant rupture during implant mammography especially with implants that have been in place for a long period of time and exhibit any hardness. This would require surgical replacement.

Implant rupture and saline leakage is also a potential in the postoperative period.

Rupture may result from any of the following; post surgical trauma, stresses or manipulations (as may occur during normal living experiences including routine and purposeful or accidental trauma such as vigorous exercises, athletics, and intimate physical contact) , unappreciated mechanical damage before or during surgery or unknown causes including so called spontaneous rupture. This is more common with the saline or inflatable implants. ***ALTHOUGH THESE IMPLANTS ARE QUITE DURABLE, THEY PROBABLY HAVE A FINITE LIFE SPAN AND WILL MOST LIKELY REQUIRE REPLACEMENT SOME TIME IN THE FUTURE.***

The outer shell of the implant is a silicone product but is distinct from the silicone gel implicated by the media as causing systemic disease. A review of those concerns is, however, warranted. The possibility of the silicone related illness has raised the question of whether this substance caused any immunological response in women with implants. There have been reports of *suspected* immunological response to silicone mammary implants. Many of the case reports suggest systemic illness with joint pain, muscle aches, fever and large lymph nodes being most frequently mentioned. Additional symptoms claim to include localized inflammation or irritation at the implant site, fluid accumulation, general malaise, swelling of joints, weight loss, arthralgia and hair loss. Some reports from medical literature refer to various combinations of such symptoms as so called silicone induced human adjuvant disease.

Review as of December 1998 of the published experimental findings and clinical experience shows that convincing evidence does NOT exist to support a causal relationship between exposure to silicone materials and the acquisition or exacerbation of a variety of rheumatic and connective tissue disorders. A causal relationship between mammary implants and the rheumatic connective tissue disorders such as scleroderma, scleroderma like disorders and other rheumatic connective tissue disorders remain to be established. If an immunologic response is suspected, removal of the prosthesis is recommended along with removal of the surrounding capsule tissue. Such patients should not be re-implanted. If you have a history of immunologic response or sensitization of foreign materials, please make this known prior to your surgery. There have been fewer than 100 cases out of the two million women implanted with breast implants who have developed these symptoms. None of these women had saline filled implants. This percentage is no higher than the normal population of women who have not received breast implants. These are extremely rare diseases and at this time there is no evidence to implicate either silicone or the saline filled implants as the causal factor. A TASK FORCE OF PLASTIC SURGEONS, INTERNISTS , EPIDEMIOLOGISTS AND RHEUMATOLOGISTS HAS DETERMINED THAT THERE IS NO REASON GIVEN THE CURRENT BODY OF KNOWLEDGE TO DISCOURAGE WOMEN FROM CONSIDERING BREAST IMPLANT SURGERY BASED ON THIS CONCERN.

The operation of breast augmentation takes approximately 1 to 1 1/2 hours and usually requires a general anesthetic. This can be done as a day surgery setting where you are admitted to the facility in the morning and following a period of recovery you are released. You should have an adult with you who can drive you home and stay with you that evening. Complications as discussed above may result in hospitalization and/or further surgery in the immediate postoperative period. This would usually be undertaken at the same facility however, depending on the availability, a second facility may be chosen which may add additional expense to the procedure. Post op course will include pain in the operative site. This should be near equal between the two sides and be controlled by medication. An increase in swelling on one side compared to the other or large discrepancy in amount of pain between the two sides may indicate bleeding and you should call the office for assistance. Postoperative nausea and vomiting is frequent with this and any procedure and is related to the combination of general anesthetic and pain medication. Nausea medications can be prescribed and if this persists feel free to contact the office. Bruising and swelling are also common and this may take the form of bruising in the area of the lower neck and area of the collar bones as well as in **the upper abdominal area**. A fullness or bloating in the abdominal region is common postoperatively and should not cause alarm. You will be placed in a tight compressive wrap for 2 to 3 days afterward and this will lessen the likelihood of bleeding or fluid collection complications. This will stay on until you are seen in the office. Bathing can be done during this period of time but no showering to avoid getting the areas wet. Upon removal of the outer wrap you will be placed in a sport bra which should be worn day and night for about one week. This will help position the breasts and apply additional pressure to minimize the risk of fluid accumulation.

DURING THE THREE WEEKS FOLLOWING SURGERY YOU SHOULD AVOID EXCESSIVE ARM MOTION INCLUDING ATHLETIC OR AEROBIC PARTICIPATION.

Normal hair washing and normal hygiene requirements can be fulfilled. Avoid direct trauma to the breast. You have sutures that will be removed approximately 3 to 7 days following the operation and once the initial ace wrap is removed you can shower and get these areas wet. Just pat the area dry and do not rub vigorously over the areas of the incisions. Should you notice any concerns regarding redness around the incision site or asymmetry in the breast which may indicate bleeding around the implant please call the office immediately for further information and instruction.

Approximately 2 to 3 weeks following the operation you will be instructed as to massage techniques to help maintain breast softness. This should be done once or twice a day according to the instructions which are given. This helps move the implant around inside the pocket and should hopefully keep the scar from becoming too tight and hard around the implants. Upon removal of the ace wraps the breast may appear extremely tight and compact. They will also appear to be high in relation to the normal crease beneath the breast. They will soften with stretching of the overlying skin and muscle and lower into a more normal position. This may take 3 to 5 weeks. Areas of nipple or breast skin numbness, as mentioned above, may be present post-operatively. This should not cause alarm.

In any operation there are risks to be considered. These include bleeding, infection, numbness, pain or discomfort, reactions to the medications or anesthetics, asymmetry, dissatisfaction with implant size and /or failure to achieve your desired appearance