REVISION AUGMENTATION MAMMAPLASTY- Capsule adjustment only, no implant change--INFORMED CONSENT

INSTRUCTIONS

This is an informed consent document that has been prepared by the Doctor to inform you about revision pf the capsule after breast augmentation, the risks, and the alternative treatments. At your first visit we will educate you as completely as possible regarding the procedure. Then, we ask that you think the procedure over so that you feel comfortable with your decision. After your surgery has been scheduled, you will return to the office for a second visit called a "rediscussion". At that time, you will meet with Patient Coordinator and the Doctor and you will be asked to sign these consent forms.

It is important that you read this information carefully and completely. Please bring these forms with you to your rediscussion visit. At that time you will initial each page, indicating that you have read the page and sign the last page, which is the consent **for surgery** as proposed by the Doctor.

GENERAL INFORMATION- Like your first surgery, or primary augmentation, this procedure is considered totally/purely elective, therefore a long consultation is essential so that you are completely educated about the procedure. Why consider revision of the capsule? There are many reasons, but it must be a decision based on *your* feelings only. It must be for you, not for or because of anyone else. The alternatives will be discussed with you at length. Each subsequent operation carries with it the same risks.

GOALS-

- Create better implant placement
- Satisfy psychological needs
- Maintain normal softness, sensitivity and function
- To enhance the previous result, for women who for personal reasons feel an improvement can be made
- To reposition an implant / revise the pocket or capsule

LIMITATIONS-

- Cannot significantly lift nipple position without adding mastopexy procedure
- Cannot create young skin or eliminate stretch marks
- Cannot completely eliminate "dents" or "ridges" from previous augmentation capsules
- Cannot eliminate asymmetry in breast shape, position, rib cage irregularities, nipple/areola size and/or position—we emphasize that everyone has asymmetry—some more that others—no one is perfect
- Cannot eliminate severe sagging. If severe sagging exists, a mastopexy may be indicated as well as implant exchange or fill..
- Cannot guarantee that a recurrence of bottoming out or shifting of the implant will not happen again or other suboptimal result, such as scar widening, etc.

INDICATIONS

- To revise the pocket or capsule
- To improve a previous result (i.e.: type, placement, migration, skin wrinkling and/or rippling, contour)
- To adjust the position of the implant inside the capsule

CONTRA-INDICATIONS:

- Active infection anywhere in the body
- Pregnant or nursing women
- Body dysmorphic disorder
- Unrealistic expectations

WHAT TYPE OF IMPLANTS ARE USED?

Silicone gel-filled implants are available in the United States as of November 2006. Breast implants that contain silicone gel had been previously restricted by the United States Food and Drug Administration (FDA) since February of 1992 to women who are participating in approved study programs with specific criteria that includes them. Dr. Taylor was approved to use the Silicone Gel implants and has done so since 2001. Saline-filled breast implants are still widely available for both breast augmentation and reconstruction. The implant pros and cons will be discussed at length to help you determine which is the best choice for you.

EVERY WOMAN IS UNIQUE—

And therefore, the operative plan will be unique. There are many choices- your previous surgery for breast enlargement was accomplished by inserting a breast implant either behind the breast tissue or under the chest muscle. Incisions are made to keep scars as inconspicuous as possible, usually under the breast. Your incision from your primary surgery will be used if possible, usually under the breast. Your implants will depend on your preferences, your anatomy and the Doctor's recommendation based on your current situation or what has already transpired. The shape and size of the breasts prior to surgery will influence both the recommended treatment and the final results. **No woman has perfect symmetry. If the breasts are not the same size or shape before surgery, they will not be completely and perfectly symmetrical afterward!** Remember, the goal of secondary augmentation is to improve a previous result.

ALTERNATIVE TREATMENT

Secondary augmentation mammaplasty is an elective surgical operation. You may choose **not** to have surgery. Other alternative treatments would consist of the use of external breast prosthesis or padding, capsulectomy or mastopexy depending on your situation. If you choose, you can use better support bras to minimize sagging, or lateral movement. If you have implants, you can choose to have them removed entirely and not undergo re-implantation.

SURGICAL TECHNIQUE-

- GENERAL ANESTHESIA
- 1-1 ½ -2-3 HOURS OF SURGERY – depending on the type / extent of revision
- OUTPATIENT
- Previous Incisions are used, usually 3-4cm FOR SALINE and 5-7cm FOR GEL IMPLANTS IN THE INFRAMAMMARY FOLD.
- DRESSINGS: 2 ACE WRAPS and SURGICAL BRA (provided) home from surgery, THEN 2 SPORTS BRAS FOR 3 WEEKS-24 HOURS—minimum—you may be asked to use the Ace Wrap also
- FOLLOW-UP VISITS: post-op day 1, 1-2-3-weeks, then 6 weeks for post–op photos
- RESTRICTIONS1-3 wks/ RETURN TO NORMAL3-6wks
- DRAINS – usually for 24 hours, but possible for up to 1 week

TRADE- OFFS

Temporary:

- Bruising-minimal
- Pain-from mild to severe
- Swelling
- Numbness-skin and nipples
- Hypersensitivity of nipples
- Restricted Activity
- Driving: Usually can't for 4-5 days

Permanent:

- Scars (usually inconspicuous)
- Change in size
- Mammograms – more difficult
- Skin stretched out when implants removed
- Difficulty shaving armpits

A Note on size and symmetry:

Due to the non-standardization of bra sizing from the manufacturers, there is NO guarantee of cup size with this surgery! The Doctor tries to match your size to be proportionate with the rest of your body. You may feel you are too large (especially for the first few months), or too small after surgery, if you are in-flexible with bra band and cup size. All women have two different breasts-no matter how similar they appear. As the breasts are not the same size or shape before surgery, they will not be completely symmetrical afterward.

Cleavage- If the implants are under the muscle, and you have very little breast tissue, you will not be able to push your breasts all the way together and get a cleavage. If you have a larger amount of breast tissue, you may be able to achieve this look, because your tissues are on top of the muscle and still can be pushed together. With the implants on top of the muscle, you may be able to push the implants together enough to create cleavage.

A note on sexual concerns (also implants and gravity)

There are changes with regards to sexual concerns that occur after breast augmentation. If nipple stimulation is important to you, it may be altered after augmentation. There is no way to predict this. If you are bent over without a bra on and especially if your skin envelope was loose before surgery, you may notice that your skin hangs off the front of the implant (as it is secured behind the muscle.) The skin and implant may also gravitate laterally (towards your sides) if you lie on your back. It is important that you realize that your partner will be aware that you have an implant. Saline breast implants are palpable. Silicone gel implants are less palpable, but can still be detected on some women. This is more pronounced the thinner you are. These are realities that you must personally decide on prior to surgery.

RISKS of SECONDARY AUGMENTATION MAMMAPLASTY SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with augmentation mammaplasty. Additional information concerning breast implants may be obtained from the FDA, package-insert sheets supplied by the implant manufacturer, or other information pamphlets required by individual state laws. We will provide these to you at your rediscussion visit.
The risk of opening up the skin and capsule around the implant are real. These must be weighed against the desire or personal need to improve the result. An individual's personal choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of women do not experience the following complications, you should remember discussing each of them with the Doctor at your previous "re-discussion" to make sure you understand the risks, potential complications, and consequences of revision of breast augmentation. A complication does not imply negligence; there are issues that occur to any doctor at certain statistical rates.

Bleeding- It is possible, though extremely unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood (hematoma). The hematoma must be removed, as it can be a nidus for infection, or cause thicker capsule formation. Do not take any aspirin or anti-inflammatory medications for ten days before surgery, as this may increase the risk of bleeding. Mild bruising does not require intervention. Bleeding that occurs a few weeks after surgery can be noticed as increased swelling. This may require additional procedures to diagnose and treat on a case by case basis.

Infection- Infection is very unusual after this type of surgery. However, if it does happen, it may appear in the immediate post operative period or at any time following the insertion of a breast implant. Subacute or chronic infections may be difficult to diagnose. It is extremely rare that an infection would occur around an implant from a bacterial infection elsewhere in the body. Should an infection occur, treatment includes antibiotics, removal of the implant and re-implantation at a later time, generally 2-3 months. You will get IV antibiotics in the OR and take them by mouth after your surgery to avoid this complication. If it does occur, you will be responsible for the OR and anesthesia cost of revision surgery. You will also need to purchase new implants. It is indicated to remove implants if an infection occurs that does not respond immediately to antibiotic therapy. It may be possible to salvage an infected implant with antibiotics, but generally this is difficult to do and not the "text book" answer.

Patient selection - Individuals with medical problems, body image disturbances, psychological disorders or unrealistic expectations may not be candidates for breast augmentation. If you have ptosis, you may require a lift procedure in addition to implants and if you are not willing to have the additional/differently located incisions, you may not be a candidate for breast augmentation. Individuals who are unwilling to undergo or incur charges for secondary surgery in the event of complication should not be considered candidates for breast augmentation.

Capsular contracture- It is normal for a thin, pliable scar tissue to form around the breast implant. The old implant will be removed from this "capsule" and the new implant placed in "capsule". A new capsule needs to be made under the pectoral muscle if your original capsule is subglandular. If the scar tissue which forms internally around the breast implant begins to tighten and make the breast round, firm, and possibly painful, this is called a "contracture". Excessive firmness of the breasts can occur soon after surgery or years later. Although the occurrence of symptomatic capsular contracture is not predictable, it generally occurs less in patients with saline implants. It is also thought to occur less frequently when the implant is placed in the retropectoral position. 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. Treatment for capsular contracture may require surgery, implant replacement, or implant removal. External pressure (closed capsulotomy) may break up scarring, but can potentially rupture the implant, so therefore it is not recommended by the Doctor.

Change in nipple and skin sensation- Some change in nipple sensation is expected right after surgery. After several months, most patients have normal sensation. Partial or permanent loss of nipple and skin sensation may occur, but is very uncommon. Some patients have hypersensitive nipples for a few months post-op. The sexual response and response to breast feeding may be permanently changed. If this would be a major hindrance to sexual satisfaction, you may want to consider not having the surgery. If you experienced some change subsequent to the primary procedure, you may experience this again.

Pain- This surgery, like others, involves an unpredictable amount and duration of pain. It may or may not be possible to predict how you will react to the pain based on previous experiences. Pain is subjective- it is truly individual to each patient. It is possible, but extremely rare, for pain to become chronic after breast augmentation. If this should occur, it would be the patient's choice to live with the pain, or have the implants removed. Usually patients report the secondary procedure is quite a bit less painful.

Skin scarring- Excessive (hypertrophic) scarring is uncommon. In rare cases, abnormal scars may result. Scars may be unattractive and of different color than surrounding skin. Additional surgery may be needed to treat abnormal scarring after surgery. The scar is often located under the breast and is not visible unless breasts are lifted. Silicone gel implants require a larger incision than saline.

Implant Rupture- Breast implants, similar to other medical devices *will* fail. Both saline and silicone implants have an "outer envelope" that will break or leak. When a saline-filled implant deflates, its salt water filling will be absorbed by the body. Rupture can occur as a result of an injury, from no apparent cause, or during mammography. It is possible to damage an implant at the time of surgery. Damaged or broken implants cannot be repaired. Ruptured or deflated implants require replacement or removal. Therefore, you will require a *minimum* of 2 operations related to implants (one to insert them and one to remove them). When they break, you may decide to have a new set of implants placed, or you may want a mastopexy (breast lift) in addition, at this time. If you choose to have them removed, and choose to not have another set placed, you may experience unacceptable dimpling, puckering, wrinkling, and other cosmetic changes. New or improved implants may be available as technology advances. The standard Manufacturer Warranty provides for a replacement implant, when one ruptures, not if you change size or other reasons. This office requires you to send in the warranty for additional benefits, which is a fee of $100, but provides an implant for the opposite side. You will also be given the catalog, serial and lot numbers for your breast implants. You are responsible for submitting the paperwork for the "upgraded warranty" if you wish to have this. Please refer to your manufacturer's paperwork for additional details.

Detection of Silent Rupture - This is the term used when a silicone gel implant envelope ruptures without the patient knowing it. Since the majority of the silicone gel stays in the capsule, the patient may not have any signs or symptoms of rupture. Sometimes though patients will report a change in the feel of the breast or other signs such as pain or tingling. The FDA recommends an MRI after three (3) years to detect silent rupture. Insurance usually will not cover this test. Physical exam done by a physician is not as effective, detecting only 30% of ruptures as compared to MRI detecting 90%.

Health Consequences of Rupture - Silicone gel may remain either intracapsular, extracapsular or move beyond the breast. If the gel moves beyond the breast it can move to the chest wall, armpit, arm or groin, liver, or lymph nodes. This can lead to granuloma formation. Epidemiologic studies do not support association of implants and rheumatic disease.

Other Reported Conditions - No evidence of association of implants with rheumatologic signs and symptoms, including but not limited to fatigue, exhaustion, joint pain and swelling, muscle pain or cramping, tingling, numbness and rashes.

Suicide: It has been reported that there is a higher evidence of suicide observed in women with implants. The reason is unknown.

Effects on Children: Studies find no increased risk of adverse health outcomes in children born to women with implants.

Cancers Concern -

Cervix – There is one study that reports an increase in incidence of cervical / vulvae cancer in women with implants. The significance and cause is unknown.

Brain – There is a recently published review of four large studies in women with implants concluding there is not an increased risk of brain cancer.

Lung – There is one study that reported increased risk but also these women were more likely to be smokers.

Implant extrusion- Lack of adequate tissue coverage, a larger than indicated implant size or infection may result in exposure and extrusion of the implant. Skin breakdown has been reported with the use of steroid drugs, after radiation therapy to breast tissue, or severe trauma. If tissue breakdown occurs and the implant becomes exposed, implant removal may be necessary. Smoking may interfere with the healing process.

Mammography -If you are over 40 years of age, pre-operative mammography is recommended prior to surgery. Post-operative mammography is performed according to American Cancer guidelines. Breast implants will make mammography more difficult. Part of the breast *cannot* be seen due to the implant, and you will require additional views. Implant rupture can occur from breast compression during mammography. Inform your radiologist of the presence of breast implants so that appropriate mammogram studies may be obtained. Ultrasound, specialized mammography and MRI studies may be of benefit to evaluate breast lumps and the condition of the implant(s). The specialized mammography may be more expensive than routine mammography, and you may be responsible for additional costs, depending on your plan.

Skin wrinkling and rippling- Visible and/or palpable wrinkling of implants will occur and is more prevalent with saline than silicone. Some wrinkling is normal and expected, especially along the lower, outer border. This may be more pronounced in patients who are very thin, or if the implants are above the chest muscle. If you had this problem with your primary augmentation, it will take time to resolve with secondary augmentation, and may not completely resolve.

Pregnancy and breast feeding- There is insufficient evidence regarding the absolute safety of breast implants in relation of fertility, pregnancy or breast-feeding. While there is no convincing evidence of any special danger of breast implants for pregnant women or their children, studies are continuing to look for possible problems. You will probably be able to nurse, however, you may notice a decrease in your milk supply (from previous children) related to the changed blood supply. If you had a subglandular augment primarily, a mastopexy or reduction nursing may not be possible.

Calcification- Calcium deposits can form in the scar tissue surrounding the implant and may cause pain, firmness, and be visible on mammography. These deposits must be identified as different from calcium deposits that are a sign of breast cancer. Should this occur, additional surgery might be necessary to remove and examine calcifications to exclude malignant changes.

Implant displacement- Displacement or migration of a breast implant may occur from its initial placement despite proper placement in the operating room and the patient's compliance with the ACE wraps and Sports Bra. The implant can migrate up or down, or outward. This may be accompanied by discomfort and/or distortion in breast shape. You may be requested to use an additional velco strap to improve the position. Occasionally ACE wrapping is used to assist in positioning. Difficult techniques of implant placement and larger than indicated implant size increase the risk of displacement or migration. Additional surgery may be necessary to correct implant malposition. This would not be done for a minimum of 6-8 weeks, since "settling" or slight downward movement, about 1 cm, is normal. Saline implants are heavier than silicone and settle more. This can lead to a more palpable implant on the lower border. Sometimes the saline implants are very palpable on thin patients.

Bottoming out- This is a sub category of displacement. Over time, the implants will continue to fall, due to gravity. Also, the larger the implant, the heavier it is, and more likely to sag—or fall. The textured implant will adhere to the tissue, mitigating this, but can have other problems with random adherence . "Bottoming out" is excessive downward movement of the implant. It can occur immediately after surgery if the patient is not compliant with the sports bra and ACE routine. If this occurs, the patient may choose to have corrective revision surgery. Smooth implants can feel softer, but can be "more slippery" and possibly not adhere to the tissues. Bottoming out causes the nipple to appear higher on the breast—pointing up.

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

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

Unusual activities and occupations- Activities and occupations which have the potential for trauma to the breast could potentially break or damage breast implants, or cause bleeding.

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

Breast disease- Current medical information does not demonstrate an increased risk of breast disease or breast cancer in women who have breast implant surgery for either cosmetic or reconstructive purposes. Breast disease can occur independently of breast implants. It is recommended that all women perform periodic monthly self-examination of their breasts, and have mammography according to American Cancer Society guidelines, and seek professional care should they notice a breast lump. If a lump is detected, it is important to inform your surgical oncologist, so that a needle biopsy does not rupture the implant.

Seroma- Fluid may accumulate around the implant following surgery, trauma or vigorous exercise. Additional treatment may be necessary to drain fluid accumulation around breast implants. The fluid may re-absorb on its own and require no other treatment, or it may periodically re-accumulate.

Long-term results- Subsequent alterations in breast shape may occur as the result of aging, weight loss or gain, pregnancy, or other circumstances not related to augmentation mammaplasty. Breast sagginess may normally occur over time. Over time the way the implant responds to the body will change. It is normal and expected for the tissue around the implant to thin with time. This may be due to the weight of the implant on the tissues and the natural aging process. It is usual for your breasts to seem smaller over time. This is probably due the tissues thinning and the ribs remodeling to a flatter profile due to the pressure of the implant. Over time, the implant will settle in a down and out position due to gravity and the force of the muscle on top. These changes may not be reversed when the implants are removed.

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

Toxic shock syndrome- This is an extremely rare complication following breast augmentation, reconstruction, or tissue expansion with silicone implants. This has been reported in the literature and is extremely rare, but may lead to septic shock, hospitalization and even death.

A note on the silicone-gel implant situation:

Silicone gel implants are approved for breast augmentation since November 2006.
Whether you will be getting saline or silicone gel implants, the outer envelope **is a silicone polymer**. The NIH and the IOM have released studies supporting the safety of saline *and* silicone gel implants, and are available if you wish to read them. The following information is included for your education.

Immune system diseases and unknown risks-

Some women with breast implants have reported symptoms similar to those of known diseases of the immune system, such as systemic lupus erythematosis, rheumatoid arthritis, scleroderma, and other arthritis-like conditions. A connection between implanted silicone and connective-tissue disorders has been reported in the medical literature. In **June 1999, the IOM released their report stating there is no scientific evidence that women with either silicone gel-filled or saline-filled breast implants have an increased risk of these diseases,** but the possibility cannot be completely excluded. If a causal relationship is established, the theoretical risk of immune and unknown disorders may be low. The effect of breast implants in individuals with pre-existing connective-tissue disorders is unknown. The absolute safety and effectiveness has not been established in patients with autoimmune diseases such as lupus and scleroderma, patients with these conditions are excluded from the programs that allow silicone gel filled implants. Other exclusions are patients with delayed wound healing and poor blood clotting or with a weakened immune system.

In December of 1998, a study was released by the NIH, which also stated that there was no scientific evidence that silicone gel-filled implants are related to these diseases.

Unlike silicone gel-filled implants, the saline-filled implants contain salt water. Any risk related to silicone gel would not be associated with saline-filled implants. However, gel-filled and saline-filled devices have a silicone envelope. An increased risk of autoimmune disease is possible even from saline implants, if it is proven to be related to the silicone envelope sometime in the future. Reliable medical laboratory tests to determine antibodies to silicone do not exist. It has not been proved that there is a relationship between silicone antibodies and disease in women with breast implants. Currently, there is insufficient evidence to state that there is a health benefit from removing either breast implant(s) and scar-tissue capsule(s) or that removal will alter autoimmune disease or prevent its potential occurrence.

In very few women who have breast implants, a variety of other symptoms and conditions have been reported, suggestive of an autoimmune multiple-sclerosis-like syndrome. Additional complaints involve the musculoskeletal, skin, nervous, and immune systems. The relationship of breast implants to these conditions has been hypothesized, although not scientifically proven. Because such disease states are rare, they are difficult to research.

Current studies have only looked for the symptoms of known autoimmune diseases, rather than the variety of symptoms that women report experiencing. Some of the reported symptoms include:

- swelling and/or joint pain or arthritis-like pain
- general aching
- unusual hair loss
- unexplained or unusual loss of energy
- greater chance of getting colds, viruses, flu
- swollen glands or lymph nodes
- rash
- memory problems, headaches
- muscle weakness or burning
- nausea, vomiting
- irritable bowel syndrome
- fever

Saline contamination-

Questions have been raised about the potential for the saline solution used to fill the implant to become contaminated with bacteria or fungus. These organisms may present a risk to the patient in the event of leakage or deflation. The saline is put in using a sterile closed injection system, thus, there should be no contamination from the operating room. These type statistics are listed in the manufacturer's booklet given to you.

Unsatisfactory result –

You may be disappointed with the results of surgery. Any of these risks can occur to any patient. Asymmetry in implant placement, breast shape and size may occur after surgery. Unsatisfactory surgical scar location or displacement may occur. Pain may occur following surgery. It may be necessary to perform additional surgery to improve your results. The Doctor will work with you to improve your result within the parameters of our office policies. Every patient is different-in their anatomy, and in their perception of their result—one person's "great" result may be another's "major disfigurement". Our policy is to help you get to the best result possible—for you. But you must work with us, and trust the expertise and recommendations of the Doctor.

OUT POINTS

However upsetting it may be, there are certain reasons that implants must be removed. The first responsibility for the surgeon is the patient's safety and welfare, and sometime implant removal without replacement is the best option to minimize additional re-operations, risks, costs, and chances of developing uncorrectable deformities.
The reasons to remove implants are:

1) Recurrence of capsular contracture
2) Recurrence of stretch deformity
3) Traction rippling without available tissue
4) Infection
5) Recurrent seroma
6) Inadequate soft tissue coverage
7) Any situation in which two previous operations

Removal/replacement of implants-

Future removal or replacement of breast implants and the surrounding scar tissue envelope involves a surgical procedure with risks and potential complications. The second operation is generally less painful, as the pocket has already been made. You will have to take a day off work, but most patients return to work in 2-3 days. You will have drains in place for the second procedure. These usually remain in place for 2-3 days. The current fee to exchange implants is $1000 per side which will be adjusted yearly for cost of living increases. This includes changing implants for any reason, including but not limited to size, symmetry and position. The fees for the operating facility and anesthesiologist are separate.

Warranty Information –

The manufacturer's warranty varies by manufacturer for older saline implants. The current warranty is similar for both manufacturers and is used for deflation before ten (10) years. If you have the standard warranty, this will provide a replacement implant for the ruptured side, and $1200 to use towards the cost of surgery. The removed implant must be returned and checked, then the reimbursement is sent. This process takes 6 to 8 weeks. You are responsible for paying all the fees prior to surgery, but the $1200 can be used as a credit. If you desire to change both sides, and have the standard warranty, you must purchase another implant at the current retail price. If you choose to change style (to silicone gel) you receive a credit for the wholesale price of the saline implant. Over time the cost of the operating room, anesthesiologist, the Doctor's fee and the implants will increase.

Health insurance -

Most health insurance companies exclude coverage for cosmetic surgical operations such as the augmentation mammaplasty and any complications that might occur from surgery. Some insurance carriers may possibly exclude breast diseases in patients who have breast implants. Please carefully review your health insurance subscriber information pamphlet.

Additional surgery neccesary-

Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with augmentation mammaplasty; other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied on the results that may be obtained.

No guarantee-

Although good results are expected, there is no guarantee or warranty expressed or implied on the results that may be obtained.

Financial responsibilities -

The cost of surgery involves several charges for the services provided. The total includes fees charged by the Doctor, the cost of implants and surgical supplies, anesthesia, laboratory tests, and outpatient hospital charges, depending on where the surgery is performed. In very unusual cases for congenital problems, insurance coverage will be attempted. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revisionary surgery would also be your responsibility.

EXTRA PAPERWORK FEES – We understand that extra documentation might be required by your employer for your surgery. As this is not considered usual and customary paperwork, there will be an additional fee of $25 for this service.

Budget-

You must have a budget for time and money. Please do not cut it too close with either one. The time factor is unknown but it is always wiser to have more than enough time, rather than not enough. The same is true for the cost. It is our office policy to discourage financing for cosmetic surgery. It is unwise to finance a cosmetic procedure, as increasing your debt load, except for income-producing assets, is unwise. Also, if revision is needed, to pay for it, you may be further in debt.

Revision surgery –

On occasion, surgical revision (due to bleeding, infection, etc.) may be indicated following the original surgery. If planned or performed within one (1) year after the surgery, there will be no charge by the Doctor, but a facility fee will be charged by the hospital for the use of the operating room. If anesthesia is required, they will have a fee as well. A nominal fee ($50-100) for supplies will be charged if the revision is performed in the office.

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). 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. The Doctor may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

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

FULL DISCLOSURE OF YOUR CURRENT AND PAST MEDICAL HISTORY IS ESSENTIAL FOR A REALISTIC OPERATIVE PLAN. ANY INFORMATION LEFT OUT MAY CHANGE YOUR RESULT. 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.

A FINAL NOTE:
This form, although lengthy, is very important. It is crucial for you to understand that you are undergoing a surgical procedure – not buying a vacation or a dress. When you do not like the dress, you can get all or most of your money back and keep shopping. That is not the case with surgery. If you are not comfortable with any aspect of this office, you are free to choose another surgeon. If you choose the Doctor, you will be operated on by the Doctor. This is a decision that requires trust and confidence- in each other. You must fully understand your personal responsibility in making the decision and trust that the Doctor will do the best surgery possible. The Doctor will trust that you, in turn, will be compliant with our post-op recommendations. When complications occur, and they inevitably do, through no fault of the Doctor, or you, we rely on this special relationship--the Doctor/patient relationship. It is this relationship that allows us to move forward, help improve the situation that has occurred, and allows everyone to be at peace about it. We will do our part to help you in every way possible.

By signing these forms, you acknowledge that we have done the following:

1. **Explained the procedure in as much detail as requested for each patient.**
2. **Read through together, with verbal explanations as needed, the consent forms and allowed ample time for questions.**
3. **Showed pictures of the range of results obtained- emphasizing that these pictures are of different individuals and the result of every person is different- including the complications of bleeding, infection, migration and asymmetry.**
4. **Provided education on the post- op period as well as what to expect for the future.**
5. **Provided the brochures from the implant manufacturer: "Making an Informed Decision" Or "Information for women considering silicone gel filled implants" and the warranty pamphlet.**

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr. _____and such assistants as may be selected to perform the following procedure or treatment:
   SECONDARY AUGMENTATION MAMMAPLASTY with capsule adjustment only- no change to the implant
   I have received the following information sheet:

   INFORMED CONSENT FOR SECONDARY AUGMENTATION MAMMAPLASTY SURGERY
   _____.
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 Doctor and her assistants or designees to perform such other procedures that are in the exercise of her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to the Doctor at the time the procedure is begun.
3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
5. I consent to the photographing or televising of the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices or body parts which may be removed.
8. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration if applicable.
9. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
   a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
   b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
   c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED
10. I, _____, have reviewed this Informed Consent with the Doctor and have had all my questions answered to my satisfaction.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-10). I HAVE BEEN ASKED IF I WANT A MORE DETAILED EXPLANATION, BUT I AM SATISFIED WITH THE EXPLANATION, AND DO NOT WANT MORE INFORMATION.

x_____
Patient or Person Authorized to Sign for Patient

Date_____ Witness _____