

BREAST AUGMENTATION-INFORMED CONSENT

INSTRUCTIONS

This is an informed consent document that has been prepared by Dr. Taylor to inform you about augmentation mammoplasty, 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 “pre-operative visit”. At that time, you will meet with the Patient Coordinator and the Doctor. It is important that you read this information carefully and completely. Please bring these forms with you to your next 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 Dr. Taylor.

GENERAL INFORMATION This operation is totally and purely elective, therefore a long consultation is essential so that you are educated as well as possible about the procedure. Why consider enlargement? The decision must be based on your feelings only. It must be for you, not for or because of anyone else.

GOALS

- Create more normal proportions
- Satisfy psychological needs
- Maintain normal softness, sensitivity and function
- Re-establish size and contour possibly changed by pregnancy or weight loss

LIMITATIONS

- Cannot stimulate breast tissue to increase in size
- Cannot create young skin or eliminate stretch marks
- Cannot eliminate severe sagging. If severe sagging exists, a lift (Samba, Wamba or Mastopexy) may be indicated as well as implants
- Cannot eliminate asymmetry in breast shape, position, rib cage irregularities, nipple/areola size and/or position—we emphasize that everyone has asymmetry—some more than others—no one is perfect
- Cannot solve personal problems

INDICATIONS

Augmentation mammoplasty is a surgical operation performed to enlarge the breasts for a number of reasons:

- To enhance the body contour of a woman, who for personal reasons feels that her breast size is too small.
- To correct a loss in breast volume after pregnancy.
- To balance breast size, when there exists a significant difference between the size of the breasts.
- As a reconstructive technique for various conditions
- Replacement of breast implants for medical or cosmetic reasons

CONTRA-INDICATIONS:

- Existing malignant or pre-malignant cancer without adequate treatment
- Active infection anywhere in the body
- Pregnant or nursing women
- Body dysmorphic disorder

WHAT TYPE OF IMPLANTS ARE USED?

Silicone gel-filled implants were approved in the United States in 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. The Doctor 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- breast enlargement is 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. The method of inserting and positioning breast implants will depend on your preferences, your anatomy and the Doctor's recommendation. The shape and size of the breasts prior to surgery will influence both the recommended treatment and the final results. The result is a combination of what you start with, plus the implant.

CHOICE OF SCAR PLACEMENT / INSERTION METHOD

There are four ways to insert a saline implant (inframammary, periareolar, axillary, umbilical) – each way has unique pros and cons. The Gel is inserted most often in the inframmary fold. The Doctor will discuss these with you.

ALTERNATIVE TREATMENT

Augmentation mammoplasty 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, or the transfer of other body tissues to enlarge breast size (in reconstruction only).

SURGICAL TECHNIQUE

- GENERAL ANESTHESIA
 - 1-HOUR OF SURGERY
 - OUTPATIENT
 - INCISIONS ARE 3-4cm FOR SALINE AND 5-7cm FOR GEL IMPLANTS IN THE INFRAMAMMARY FOLD.
 - DRESSINGS: 2 ACE WRAPS and SURGICAL BRA (provided) home from the surgery center THEN 2 SPORTS BRAS FOR 3 WEEKS- 24 HOURS—minimum—you may be asked to use the ACE wrap.
 - FOLLOW-UP VISITS: post-op day 1, 1-2-3-weeks, then 6 weeks for post –op photos
 - RESTRICTIONS 1-3 wks, RETURN TO NORMAL 3-6wks
- Driving: if not taking pain medications and driving automatic transmission 4 – 5 days

TRADE- OFFS

Temporary:

- Bruising-minimal
- Pain-from mild to severe
- Swelling
- Numbness-skin and nipples
- Hypersensitivity of nipples
- Restricted Activity

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! Dr. Taylor 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, All women have two different breasts-no matter how similar they appear. If 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. Symmastia can occur if the implants are pushed too close to the middle as they can shift without the muscle tissue to hold them in place. This can also occur in “under the muscle” placement if the muscle fibers disrupt after surgery.

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 AUGMENTATION MAMMAPLASTY SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with augmentation mammoplasty. 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 preoperative visit.

An individual's 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 discuss each of them with The Doctor to make sure you understand the risks, potential complications, and consequences of breast augmentation. You must understand that you take personal responsibility for making the decision to proceed. These complications have occurred, and no one is immune to these risks.

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. If this scar tissue (which forms internally around the breast implant) tightens and makes the breast round, firm, and possibly painful this is abnormal. This excessive firmness of the breasts can occur soon after surgery or years later. It is thought to occur less frequently when the implant is placed in the retropectoral position. The incidence of symptomatic capsular contracture is not predictable. Capsular contracture may occur on one or both sides. 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 done by the Doctor. The Doctor will not replace implants after two incidences of capsular contracture. If a capsule forms that is too large, the implant can “shift” around or move on a daily basis. This can be bothersome especially when laying down flat without a bra on. Wearing a support bra to bed can help with this.

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.

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. Rarely, patients can complain of pain for many months. Even more rare, but possible, is pain that does not resolve and may require implant revision or removal.

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. If the scar is placed around the areola, or if you require a lift, it will, of course leave a more noticeable scar. All scars are pinkish for a few months after surgery. There are many new therapies available to improve the scar.

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 manufacturers 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.

Lymphoma-ALCL: see page 9

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 palpable wrinkling of implants can occur with saline and silicone implants. 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. Over time, the implants may seem to wrinkle more, probably due to tissue thinning. The occurrence of rippling is decreased with silicone gel implants. Visible rippling along the sternal border can occur if the pectoral muscle is released over the sternal border in the effort to place the implants closer together, and is more pronounced with saline implants. Wrinkles or ripples seem to get worse over time for the very lean patients. Changing from saline to silicone gel may not eliminate this completely. If you having a revision to address this issue, are not comfortable with this possibility, you may want to consider taking out the implants and not replacing them, as some ripples may not totally resolve with revision.

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. You may have more sagginess of the breasts related to the increased skin stretching during pregnancy. Your breasts will look and feel different from their pre-pregnant state.

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. . 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 and expected and can take 6-12 months to occur. 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 settle, 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 mammoplasty. 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.

Hormones and Risk of Deep Venous Thrombosis (DVT)

While we realize it may be inconvenient for you, we do recommend stopping all extra hormones prior to surgery, because these can increase your risk for a blood clot in your leg. For our patients who are on birth control pills, please discontinue these-- but don't forget another type of barrier contraception! For our more mature patients taking HRT (hormone replacement therapy), we regret you may have increased symptoms related to menopause, but once again, we believe it is worth the inconvenience to increase your safety.

A note on the silicone-gel implant Silicone gel implants are approved for breast augmentation since December 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 erythematosus, 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.

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

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 at any time 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.

Removal/replacement of implants

Revision procedures and future removal or replacement of breast implants and the surrounding scar tissue envelope involves a surgical procedure with risks and potential complications. The "Secondary" operation is generally less painful, as the pocket has already been made. You will have to take at-least a day off work, but most patients return to work in 2-3 days. You may have drains in place for the second procedure. Costs of secondary procedures are the responsibility of the patient.

Warranty Information

The manufacturer's warranty varies by manufacturer and by the type of implant you and the Doctor choose. The Manufacturers warrantly will be given to you at the preoperative visit.

Health insurance

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

Additional surgery necessary 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 mammoplasty; other complications and risks can occur but are even more uncommon. . The practice of medicine and surgery is not an exact science. **Individuals who are not willing to undergo and/or incur charges for any additional surgery necessary should not proceed with breast augmentation.** See CosmetAssure Benefits brochure.

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, anesthesia, and outpatient hospital charges, depending on where the surgery is performed.

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, than not enough. The same is true for the cost. It is our office policy to discourage financing for cosmetic surgery. If a complication does occur and a surgical revision is needed you could become further in debt.

Revision policy- On occasion, surgical revision for emergency (due to bleeding, infection etc.) may be indicated following the original surgery. If this occurs within 30 days of surgery refer to your CosmetAssure Benefits brochure. If planned or performed within one (1) year after the surgery, there will be no charge by The Doctor. A facility fee will be charged by the hospital for the use of the operating room and there will be a fee for the Anesthesiologist, ranging from \$1000-\$2000. A nominal fee (\$200-\$300) for supplies will be charged if the revision is performed in the office.

Implant Types- implants are available from 3 manufacturers in the US, and a variety of fillers and shell types. These will be discussed at length so you are comfortable with the decision. There are pros and cons to each type.

ALCL facts: According to the U.S. Food and Drug Administration (FDA), less than one hundred people in the United States have been diagnosed with breast implant-associated ALCL, an extremely rare cancer.

Although implant-associated ALCL is extremely rare, the FDA believes that women with breast implants may have a very small but increased risk of developing this disease in the tissue capsule the body forms around an implant over time. ALCL may also be found in the lymph nodes and the skin.

At this time, data appears to indicate that the incidence of ALCL is very low, even in breast implant patients and is estimated to be between 1 in 70,000 to 1 in 500,000.

Currently, it is not possible to identify a type of breast implant (silicone, saline or polyurethane) or a reason for the implant (reconstruction versus aesthetic augmentation) that is associated with a smaller or greater risk.

Overall, lymphomas of any type that occur in the breast are rare, accounting for only 1 to 2% of all non-Hodgkin's lymphomas. Most breast lymphomas have a B-cell phenotype. However, implant-associated ALCL has a T-cell phenotype.

Implant-associated ALCL tends to remain confined around the breast implant. Most patients have a good prognosis when they receive the appropriate treatment.

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 car 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 – you can't take it back! Additionally, the Doctor is not trying to sell you surgery – she will tell you if you shouldn't have it. If you are not comfortable with any aspect of this office, you are free to choose another surgeon. If you choose Dr. Taylor you will be operated on by her. 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 Dr. Taylor will do the best surgery possible. Doctor Taylor 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 Breast Augmentation

I hereby authorize Dr. Taylor and such assistants as may be selected to perform the following procedure or treatment:

Breast Augmentation

I have received the following information sheet:

INFORMED CONSENT BREAST AUGMENTATION

1. 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 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.
2. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involves risk and the possibility of complications, injury, and even death.
3. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
4. 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.
5. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
6. I consent to the disposal of any tissue, medical devices or body parts which may be removed.
7. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
8. 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
9. 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 (1-9). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date _____ Witness _____