

My Preferences and Information I Fully Understand and Accept:

I, _____, have read the following materials sent to me by Dr. Janis about breast augmentation in their entirety:

- Overview of Breast Augmentation
- Breast Augmentation Pamphlet
- Patient Preferences Document

Before visiting with Dr. Janis, the following are my preferences and choices. I understand that if Dr. Janis feels that my choices might have negative short-term or long-term effects on my tissues or my chances for the best result with the least risk of complications, he will discuss these issues with me during our consultation.

_____ I understand that Dr. Janis can achieve virtually any size breast that I choose, but Dr. Janis is limited by the characteristics of my tissues that we can't change. I also understand that the choices I make, particularly with respect to implant size, can affect the appearance of my breasts as I get older and can affect my risks of having complications or needing additional operations in the future.

Please initial one of the following with regard to the BREAST SIZE YOU DESIRE:

_____ I want a MINIMAL amount of enlargement.

_____ I want to be AS FULL AS I CAN BE AND ACHIEVE A NATURAL APPEARING BREAST THAT IS SAFEST FOR MY TISSUES LONG-TERM. I leave the choice of implant size under these circumstances entirely to Dr. Janis, and will accept the size of breast that he feels is safest for my tissues long-term.

_____ I want a SPECIFIC SIZE BREAST—at least a _____ cup size AND at least a _____ cc implant. (Please fill in ALL blanks)

Please initial one of the following with respect to CHOICE OF BREAST SIZE AND RISK OF FUTURE PROBLEMS:

_____ I WANT A BREAST SIZE THAT WILL HAVE THE LEAST CHANCE OF CAUSING FUTURE SAGGING, COMPLICATONS, OR NEED FOR ADDITIONAL PROCEDURES SUCY AS A BREAST LIFT. I understand that Dr. Janis will choose an implant that will produce the fullest breast possible that is safest long-term, unless I specify a smaller or larger breast. I leave the choice of implant size entirely to Dr. Janis based on his evaluation of my tissues and body proportions. I understand and accept that Dr. Janis cannot guarantee a cup size of my result, and I will not request a larger implant following my augmentation.

_____ I WANT A SPECIFIC BREAST SIZE, EVEN IF IT MIGHT BE LARGER THAN IDEAL FOR MY TISSUES. If I want a larger implant than Dr. Janis feels is optimal for my tissues, I understand that I may not have a natural appearing breast. I am willing to accept all responsibility for appearance and increased risks of re-operations, complications, deformities, and additional costs and time off work and normal activities in the future that may result from my selecting an implant that is larger than ideal for my tissues.

Please initial one of the following with respect to HOW YOU WOULD LIKE YOUR BREASTS TO LOOK:

Three to six months after my augmentation (after my tissues relax), I want the upper portion of my breast to appear:
_____ Inwardly curved, NOT FILLED IN THE UPPER PORTION OF THE BREAST.

_____ FULL IN THE UPPER BREAST, with a straight or slightly outwardly curved profile in side view.

_____ EXTREMELY FULL, WITH A VERY BULGING UPPER BREAST. I understand and accept that this choice produces a breast that does not appear natural and may have excessive bulging with an unnatural appearing transition from the upper chest to the breast. I also understand that an excessively large implant can cause damage to my tissues long-term that could cause me to need additional operations or have permanent deformities, but I want the large implant regardless of those possible consequences.

My Preferences and Information for Breast Augmentation (cont'd)

IMPLANT SHAPE I prefer: Shaped or Anatomic Round

IMPLANT SHELL TYPE I prefer: Textured Smooth

IMPLANT MANUFACTURER I prefer: McGhan Medical Mentor Other: _____
 I want Dr. Janis to choose and will abide by his choice

IMPLANT SIZE I prefer:
 I want an implant that contains at least _____cc of saline (if you have an opinion). If I do not specify a number of cc's that I want in my implant, I am leaving the decision entirely up to Dr. Janis, and I will accept his judgment regardless of my breast size following surgery.

I have absolutely no specific preference for the number of cc's in my breast implant, and I want Dr. Janis to choose based on his evaluation of my tissues and proportions. If I ask Dr. Janis to choose the appropriate size implant that is best for me, I will abide by his choice, understanding that he will fill my breast as much as he feels it can be filled safely, without producing additional risks or tradeoffs.

If, after surgery, for any reason I desire a different size implant, I understand and accept that I must specify the exact type and size of implant in cc's, and that I am totally responsible for all costs associated with changing my implants, including surgeon fees, anesthesia fees, laboratory costs, and surgical facility fees. Further, I will not expect Dr. Janis to re-operate to correct any problems that may occur as a result of my requests for a larger or different implant.

IMPLANT POCKET LOCATION I prefer:

I prefer my implant be placed UNDER muscle. I have read and fully understand and accept the tradeoffs of placing an implant under muscle.

I prefer my implant be placed ABOVE muscle. I have read and fully understand and accept the tradeoffs of placing an implant above muscle, and I understand and accept that I may see visible implant edges or other irregularities if the implant is placed above the muscle.

I do not have a preference for over or under muscle, and I want Dr. Janis to choose according to my tissue requirements. I have read and fully understand the tradeoffs of placing an implant either over or under muscle.

INCISION LOCATION I prefer:

Under the breast Around the areola In the armpit In the belly button

I would like Dr. Janis to choose my incision location based on his assessment of my needs and optimal control during the operation, and I will abide by his decision.

Factors Following My Breast Augmentation Dr. Janis Cannot Control

I, _____, have read Dr. Janis' informational materials. The following is essential information that I must understand and accept before having Dr. Janis perform my breast augmentation. I have discussed each of these with Dr. Janis and fully understand and accept the tradeoffs, risks, costs, and outcomes associated with each item.

_____ From my reading of Dr. Janis' educational material, and after my patient educator consultation, I understand and accept that there are several factors related to my individual tissue characteristics, how I heal, and how my tissues respond to my breast implants that Dr. Janis cannot predict by tests before surgery, and cannot control after surgery.

INFECTION

_____ I fully understand and accept that if I develop an infection following my augmentation, Dr. Janis will remove one or both my breast implant. If an implant(s) is/are removed secondary to infection, Dr. Janis will discuss the pros and cons of replacement with me. Never replacing implants may also be an option to minimize further re-operations, risks, and costs to me. If I decide to replace the implant, a period of time will be required following removal to allow my breast tissue to heal and soften (this is usually is 3-6 months). I further understand and accept that, if implant removal is ever required for any reason, that deformities may result that may not be totally correctable.

_____ I understand and accept that Dr. Janis must work with what I bring him to work with, and that he cannot change the qualities of the tissues of my breasts that affect stretch following surgery or how I will heal. I also understand and accept that Dr. Janis cannot perform tests before surgery, or in any other way predict 1) how my skin will stretch following my augmentation, and 2) how my body will heal or not heal following my augmentation.

TISSUE STRETCH

My tissue characteristics and stretch of tissues following my augmentation: How they can affect my results, need for additional surgery, and costs

_____ If my tissues stretch excessively in any area following my augmentation, deformities can result over which Dr. Janis has no control. These deformities include the following:

- 1) excessive sagging or "bottoming out" of the breast with the implant too low and the nipple pointing excessively upwards,
- 2) shift of the implants to the sides with widening of the gap between the breasts,
- 3) thinning of tissues over the implant allowing the implant to become visible or palpable (able to be felt) in any area, and
- 4) visible rippling in any area that can result when the implant pulls on the overlying tissues.

_____ I understand and accept that any or all of these deformities can occur in one or both breasts, and do not occur equally on the two sides. I also understand and accept that the larger breast implant I choose or my breasts require for optimal aesthetic results, the greater the risk of these deformities occurring. Although breasts never match exactly on the two sides, if any of these deformities occur, differences in the two breasts may be more noticeable and may not be correctable.

_____ I understand and accept that if any or all of the deformities caused by tissue stretch listed above should occur, even though the deformity may be visible, that Dr. Janis alone will determine whether additional surgery is needed. Dr. Janis will base this decision on whether he feels the potential benefits outweigh the potential risks of additional surgery and whether he feels I will get predictable improvement from additional surgery. I agree to abide by Dr. Janis' decisions in all matters pertaining to whether or not additional surgery is performed.

_____ I understand and accept that if my tissues stretch excessively for any reason following my augmentation, that additional surgery will not change the qualities of my tissues that allowed them to stretch in the first place. As a result, additional surgery to correct stretch deformities is unpredictable at best due to the limitations my tissues impose, and that surgery for any of the stretch deformities listed above may not successfully correct the deformity, and that any or all of these deformities can occur again if my tissues stretch again.

HEALING CHARACTERISTICS**My healing characteristics following my augmentation: How they can affect my results, need for additional surgery, and costs**

_____ I understand and accept that Dr. Janis has absolutely no control over how my body heals following my breast augmentation, and that he cannot predict (by tests prior to surgery) or control my individual healing characteristics.

_____ I understand and accept that my body will form a lining (capsule) around my breast implant following my augmentation, and that the capsule around the implant may contract (tighten) excessively, causing a variety of deformities that may require additional surgery and despite additional surgery, may be uncorrectable and require implant removal. The capsules that form and the amount that they tighten are never equal on both sides, so the effects of the capsule on each breast are usually different.

_____ I understand and accept that there are no tests or medical information that can accurately predict whether my capsules will tighten excessively, and that following my augmentation, Dr. Janis has no control over how my body forms the capsule or how much the capsule will tighten or cause deformity.

_____ I understand and accept that any or all of the following deformities can result from how the capsule forms and tightens, and that Dr. Janis cannot predict, prevent, or control the occurrence of any of these deformities:

- Closing of a portion of the lower implant pocket (can be mild or severe), causing slight or significant upward displacement of the implant, and raising the fold under the breast leaving the incision scar below the fold (if the incision was made under the breast)
- Closing of a portion of the outside of the implant pocket, causing flattening of areas of the outside contour of the breast and inward displacement of the implant.
- Excessive firmness of the implant or breast
- Visible edges or bulging deformities in any area of the breast
- The quality of the scar that I will form wherever my incision is located.
- The effects of my body healing and scarring in the area of the incision, adjacent areas to the incision or breast, or any area of the breast.
- Discomfort or pain in areas of the breast
- Change in sensation or loss of sensation in any area of the breast or adjacent areas.
- Occurrence of lymph node enlargement or small bands near the incision caused by incision or obstruction of small lymph vessels (both of which usually subside without treatment in 3-6 weeks).

_____ I understand and accept that any or all of these deformities can occur in one or both breasts, and do not occur equally on the two sides. Although breasts never match exactly on the two sides, if any of these deformities occur, differences in the two breasts may be more noticeable and may not be correctable.

_____ I understand and accept that if any or all of the deformities caused by my healing characteristics or the characteristics of the capsule (lining) around my implants occur, even though the deformity may be visible, that Dr. Janis alone will determine whether additional surgery is needed. Dr. Janis will base this decision on whether he feels the potential benefits outweigh the potential risks of additional surgery and whether he feels I will get predictable improvement from additional surgery. I agree to abide by Dr. Janis' decisions in all matters pertaining to whether or not additional surgery is performed.

_____ I understand and accept that if any of the deformities listed above occur following my augmentation, that additional surgery will not change the qualities of my tissues and healing characteristics that caused the deformity in the first place. As a result, additional surgery to correct these deformities a) is unpredictable at best due to the limitations of my tissues and healing characteristics, b) that surgery for any of the deformities listed above may not successfully correct the deformity, and c) that any or all of these deformities can occur again after additional surgery because of my healing characteristics.

RESPONSIBILITY FOR COSTS ASSOCIATED WITH ADDITIONAL SURGERIES

_____ Since Dr. Janis cannot predict or control my tissue characteristics or healing characteristics and how they will affect my chances of developing any of the deformities listed above related to tissue stretch and thinning or capsule or scar tissue formation following my augmentation, I understand and accept that should any of the any of the deformities

listed above occur, if surgery is necessary to try to improve any of the following conditions, that *I will be personally responsible for all costs associated with any surgery that is performed (please initial beside each number indicating your complete understanding and acceptance of all costs associated with surgery for each deformity):*

- 1) _____ Excessive sagging or “bottoming out” of the breast with the implant too low and the nipple pointing excessively upwards,
- 2) _____ Shift of the implants to the sides with widening of the gap between the breasts,
- 3) _____ Thinning of tissues over the implant allowing the implant to become visible or palpable (able to be felt) in any area, and
- 4) _____ Visible rippling in any area that can result when the implant pulls on the overlying tissues.
- 5) _____ Closing of a portion of the lower implant pocket (can be mild or severe), causing slight or significant upward displacement of the implant, and raising the fold under the breast leaving the incision scar below the fold (if the incision was made under the breast)
- 6) _____ Closing of a portion of the outside of the implant pocket, causing flattening of areas of the outside contour of the breast and inward displacement of the implant.
- 7) _____ Excessive firmness of the implant or breast
- 8) _____ Visible edges or bulging deformities in any area of the breast
- 9) _____ Discomfort or pain in areas of the breast
- 10) _____ The effects of my body healing and scarring in the area of the incision, adjacent areas to the incision or breast, or any area of the breast.
- 11) _____ Discomfort or pain in areas of the breast
- 12) _____ Change in sensation or loss of sensation in any area of the breast or adjacent areas.
- 13) _____ Occurrence of lymph node enlargement or small bands near the incision caused by incision or obstruction of small lymph vessels (both of which usually subside without treatment in 3-6 weeks).

_____ I understand and accept that Dr. Janis does not accept insurance or any third party reimbursement for any type of additional surgery that may be necessary following my augmentation, and that I will be personally responsible for prepaying all costs of any additional surgery at least two weeks prior to the scheduled surgery. If I choose to pay by credit card, I understand and accept that I agree to sign additional documents authorizing full payment by my credit card company. Dr. Janis will provide me with copies of my operative note from my surgery, but I assume all responsibility for any filing of insurance and understand that Dr. Janis and his staff will not pursue payments from any third party.

_____ I understand and accept that costs of any additional surgery following my augmentation will likely exceed the costs of my original augmentation surgery, and that costs are determined by the complexity and length (time) of the surgery required. Fees for additional surgery will include laboratory fees, electrocardiogram fees if I am over 40 or have any heart condition, possible mammogram or MRI imaging fees, Dr. Janis’ surgeon fees, anesthesia fees, surgical facility fees, and costs of take home medications. I accept personal responsibility for all of these fees, and in addition, I understand and accept that I may have additional costs associated with time off work or normal activities.

_____ I understand and accept that Dr. Janis alone sets his fees for all surgeries he performs, that these fees are not negotiable for any reason by any party, and must be pre-paid at least two weeks prior to surgery.

_____ If following my breast augmentation, any additional surgery for the reasons listed above becomes necessary, and I later choose to dispute any of the items above for which I have indicated my full understanding and acceptance, I agree to pay any and all of Dr. Janis’ costs, including any attorney’s fees, court costs, or any other costs associated with resolving the dispute.

_____ I have read all of Dr. Janis’ informational materials. I have had an opportunity to ask questions and have had all of my questions answered to my satisfaction. I will have an additional opportunity to ask Dr. Janis questions during our consultation.

I feel fully informed, and have had an opportunity to have all of my questions answered to my satisfaction.
Signed this _____ day of the month of _____, 2004.

Patient

Witness

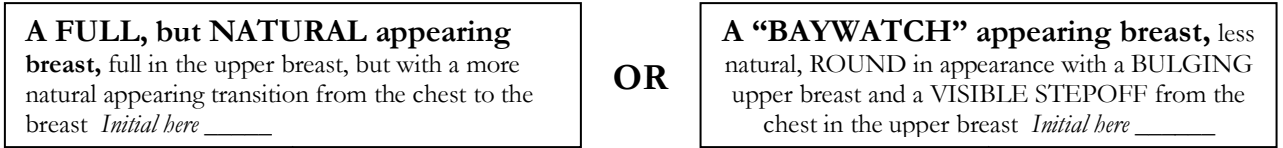
Patient

Witness

_____ I have been given a copy of this document for my personal records.

To Help with Your Augmentation Choices An Outline of Decisions

Which breast “look” would you like to achieve from breast augmentation surgery?



Please choose ONE of the following alternative methods of producing a FULL but NATURAL APPEARING BREAST:

Please proceed to Page 2

An ANATOMIC SHAPED IMPLANT, Filled Within Manufacturer’s Recommended Fill Range
Initial here _____

Potential Benefits	Potential Tradeoffs & Risks
1. Adequate fill to prevent upper shell collapse while preserving manufacturer’s warranty	1. More expensive
2. Provides natural appearance while allowing adequate fill to prevent upper shell collapse	2. Requires more technical expertise by surgeon to avoid excessively large pocket for implant
3. Maintains upper breast fill better because upper pole does not collapse	3. Shell slightly thicker (by a few ten-thousandths of an inch) compared to non-textured, smooth implants. Thicker shell may increase durability, but may be easier to feel under thin tissues
4. Implant shape more like a natural breast shape when filled adequately to prevent upper shell collapse	4. May feel slightly firmer than an under filled implant
5. Filled adequately to minimize risks of under fill rippling or wrinkling	

OR

A ROUND SHAPED IMPLANT, Filled Within Manufacturer’s Recommended Fill Range
Initial here _____

Potential Benefits	Potential Tradeoffs & Risks
1. Can achieve same natural look as anatomic, BUT see tradeoff number 1 at right	1. Achieves natural upper pole appearance, but only if upper pole shell collapses to some degree
2. Cheaper than anatomic	2. Upper shell collapse may shorten life of implant shell, may require replacement sooner
3. May feel the shell slightly less if smooth round, because smooth shell is slightly thinner than textured shell	3. Shell collapse may increase risks of visible rippling or wrinkling in various areas of the breast
4. Easier for some surgeons to use, no special requirements in surgical technique	4. Fill amount inadequate to prevent upper shell collapse may increase risks of audible “sloshing”

Cont’d from Page 1

From page 1, you requested: →

A “BAYWATCH” appearing breast, less natural, ROUND in appearance with a BULGING upper breast and a VISIBLE STEPOFF from the chest in the upper breast *Initial here* _____

Please choose ONE of the following alternative methods of producing a “BAYWATCH” APPEARING BREAST:

(Less natural, ROUND in appearance with a BULGING upper breast and a VISIBLE STEPOFF from the chest in the upper breast)

A ROUND SHAPED IMPLANT, OVERFILLED Past Manufacturer’s Recommended Fill Range

Initial here _____

Potential Benefits	Potential Tradeoffs & Risks
1. Less risk of shell collapse, folding, failure if adequate filler is added to prevent upper implant shell collapse	1. Slightly firmer than an under filled implant
2. Additional filler to prevent upper shell collapse also decreases risks of visible wrinkling or rippling in the breast	2. If filled past manufacturer’s recommended fill, may void manufacturer’s warranty
3. Less expensive than anatomically shaped implants	3. When a round implant is filled adequately to prevent upper shell collapse, the upper pole of the implant bulges more than a similar anatomically shaped implant
4. If round, smooth shell, shell may be slightly thinner and harder to feel in the breast	

OR

An EXCESSIVELY LARGE ROUND IMPLANT Filled within Manufacturer’s Recommended Fill Range

(It is possible to select an excessively large implant and fill it within manufacturer’s recommended range to produce the desired excessive, unnatural bulging of the upper breast)

Initial here _____

Potential Benefits	Potential Tradeoffs & Risks
1. Achieves the desired excess upper fullness and step off as the overfilled round, but increases risks of shell folding	1. If filled within manufacturer’s recommended range and compressed into a tight pocket, shell folding is very likely to occur. Shell folding may shorten shell life and require implant replacement sooner
2. Preserves the manufacturer’s warranty	2. An implant that is excessively large for your tissues to support may cause any or all of the following: excessive skin stretch, excessive sagging of the breast, excessive thinning of the skin, implant edges that you may feel or see, visible rippling or wrinkling from traction on the tissues, necessity of earlier re-operation for sagging or other problem listed above

_____ I have been informed, and I understand that **NO IMPLANT, REGARDLESS OF SIZE OR SHAPE**, can guarantee upper breast fullness long-term, and the larger the implant I select, the more likely stretch of the lower breast envelope will allow loss of upper fullness.

Patient Name: (please print) _____
 Patient Signature _____

Date: _____

Witness Name: (please print) _____
 Witness Signature _____

Date: _____

How Did We Do Informing You?

I, _____, have read Dr. Janis' informational materials. I have also had an opportunity to ask questions and have had all of my questions answered to my satisfaction. I will have an additional opportunity to ask Dr. Janis questions during our consultation.

To assure that I thoroughly understand and accept the essential information about risks and tradeoffs, I am asked to answer the following questions and initial my answers.

Please initial the following ONLY IF YOU FULLY UNDERSTAND AND ACCEPT THE INFORMATION WE HAVE GIVEN YOU:

_____ I fully understand and accept that perfection is not an option, improvement with tradeoffs is the best we can hope for. No choice we can make is without tradeoffs and risks.

_____ I fully understand and accept that no woman has two breasts that match, and that no surgeon can produce two breasts that exactly match. I understand and accept that Dr. Janis will try his best to equalize my breasts as much as visually possible given my tissues and their limitations, but my breasts will not match after surgery.

_____ I fully understand and accept that the larger we make my breasts, the worse they will look as I get older, the greater the risks of tissue thinning and/or visible rippling, and the greater the risk of my needing additional surgeries with additional risks and costs.

_____ I fully understand and accept that Dr. Janis cannot and will not guarantee me a specific cup size breast, because cup size is not a consistent or predictable clinical measurement, cup size varies among bra manufacturers, and I may choose to wear a bra that is larger or smaller to produce a certain look in my breasts or for comfort or style reasons.

_____ I fully understand and accept that if I have thin tissues in any area, that I will likely feel the edge or the shell of my implant. If I can feel my ribs with my finger beneath my breast, I may feel the edge of my implants. If my tissues are extremely thin, I may even see a portion of the implant shell or an implant edge. Dr. Janis will make every effort to provide as much tissue coverage as my tissues will allow minimizing these risks, but he is limited by the quality and thickness of my tissues.

_____ I fully understand and accept that Dr. Janis cannot predict or control the amount that my tissues may stretch following augmentation. The larger the implant we choose, the more the tissues will stretch, but even with an implant that seems appropriate for my tissues, it is possible for my tissues to stretch excessively or unevenly in one breast or the other. If this occurs, breast shape or position may be different on the two sides, nipple tilt or position may be different, and additional surgery may be required to attempt to correct excess stretching deformities. Because this problem cannot be predicted or prevented, costs of additional surgery are totally my responsibility, including surgeon fees, anesthesia fees, and surgical facility fees. Additional surgical procedures carry additional risks, and do not guarantee correction of stretch deformities.

_____ I fully understand and accept that if I develop infection in either breast at any time, that Dr. Janis will remove one or both implants, and may recommend not ever replacing either implant due to risks of re-infection and/or capsular contracture, either of which could necessitate multiple re-operations and/or permanent deformities.

_____ I fully understand and accept that capsular contracture (contraction of the lining that forms around every breast implant), although not a medical complication, may cause me to need additional surgery. There are no tests or facts in my medical history that will allow Dr. Janis to predict whether I will develop a capsular contracture in one or both breasts, and there is no implant or surgical techniques that can assure that I won't develop capsular contracture. If I develop capsular contracture, I fully understand and accept that Dr. Janis will re-operate on my breasts ONLY ONCE to remove or correct the capsular contracture. If I develop another capsular contracture after the first re-operation, Dr. Janis will recommend REMOVAL OF BOTH IMPLANTS WITHOUT IMPLANT REPLACEMENT as the safest and best option to prevent an excessive number of re-operations. Additional re-operations could result in greater risks of tissue thinning and/or visible rippling, greater risks of my needing additional surgeries with additional risks and costs, and could result in permanent deformities. I accept full responsibility for all costs associated with correction of capsular contracture, including surgeon fees, anesthesia fees, implant costs, laboratory and drug costs, and surgery center or hospital costs.

_____ I fully understand and accept that if my implants ever need to be removed for any reason, the appearance of my breasts will be compromised. The larger the implant that I choose, the worse the appearance of my breasts will be, and the greater the risks of my needing additional surgery with additional costs and risks.

_____ I fully understand and accept that if I choose a round shaped implant, that I will then have to choose between filling the implant to manufacturer’s recommendations and risking implant shell rippling, folding, or premature failure, OR request that Dr. Janis overfill my implant past manufacturer’s recommendations and possibly void the manufacturer’s warranty. If I choose a pre-filled, round saline implant, I accept that the implant may be under-filled and accept the risks of shell rippling, folding, or premature failure.

_____ I fully understand and accept that I will be totally responsible for additional surgical fees, surgery facility fees, and anesthesia fees, as well as possible additional lost time off work or normal activities for three specific conditions: 1) Capsular contracture (excessive firmness or pocket closure in any area that causes implant displacement or deformity), 2) any deformity caused by excessive stretching of the breast skin in any area, producing excessive “bottoming” or implant displacement, excessive sagging, or other stretch deformity, and 3) any exchange of breast implants for any reason, including a change in breast implant size or shape. If other complications occur, Dr. Janis will not charge any surgical fee for my treatment, but I am responsible for surgery facility fees, lab test fees, and anesthesia fees as well as additional time off work and travel costs.

_____ I understand and accept that I am fully responsible for all additional charges for Dr. Janis’ surgical fees, implant costs, surgery center fees, anesthesia fees, lab and drug fees, and costs of time off work for recovery for the following conditions: 1) treatment of any capsular contracture or pocket closure problem that could result in breast deformity or malposition of my implants, 2) treatment of any problem that may result from excessive stretch of my tissues, causing malposition of my implants or excessive tissue thinning, or 3) any exchange of breast implants for any reason, including a change in breast implant size or shape.

_____ I clearly understand and accept that all choices and decisions that Dr. Janis makes will be based ENTIRELY ON MY WRITTEN REQUESTS in the documents that he provides me during our consultation and preoperative communications, NOT ON ANY VERBAL DISCUSSIONS NOT VERIFIED IN MY WRITTEN REQUESTS.

_____ I understand and accept that Dr. Janis cannot read my mind and it is my complete responsibility to be absolutely honest in my written requests. I have absolutely no other requests, expectations, or agendas other than those specifically defined in the written documents I have completed and signed.

_____ I am confident and comfortable that I have completely and honestly specified my desires and expectations in the written documents I have completed for Dr. Janis. I also understand that if any of this information changes prior to surgery, it is my responsibility to see that new, written documents are completed and signed by me. I understand and accept that Dr. Janis will NOT consider any verbal communications without written confirmation and documentation signed by me.

_____ If, for any reason in the future, I commence, join in, or in any other manner attempt to assert any legal claim or cause of action against Dr. Janis for any item in this form that I have specifically acknowledged responsibility for by my initial or signature, I agree to pay all of Dr. Janis’ attorneys fees associated with defending my claim or cause of action.

I feel fully informed, and have had an opportunity to have all of my questions answered to my satisfaction. Signed this _____ day of the month of _____, 2004 in the presence of the witness listed below.

Patient

Witness

Patient

Witness

_____ I have been given a copy of this document for my personal records.

Will Anyone Else Be Involved in Your Choices or Decision-Making?

If any other person will be involved in the choices or decisions you will make regarding your augmentation, or will be involved in any discussions with Dr. Janis or his staff following surgery regarding your choices or your result, they will need to be as informed as you are to prevent their misinterpreting your choices, your decisions, or your result. They will need to understand all of the choices, tissue limitations, tradeoffs, and risks that we discuss with you. We will provide you with the necessary information and copies of your documents to review and discuss with them, but you are responsible for encouraging them to become familiar with your information and choices.

Will **anyone else** be involved in the choices or decisions you will make regarding your augmentation, or in any discussions with Dr. Janis or his staff following surgery regarding your choices or your results?

Yes /No _____ (Please circle one and initial)

If yes, please specify: Name: _____ Relationship: _____.

Please read and if you understand and accept the statements, initial each of the following items:

_____ Before my patient educator consultation, I was asked if anyone else would be involved in the choices or decision-making process for my breast augmentation, and I was encouraged to bring them with me during each consultation visit or have them participate in patient educator telephone calls.

_____ **If I do not specify in this document another person who will be involved in my choices or decision-making, I specifically request Dr. Janis and his staff to have no discussions following surgery about any aspect of my care or results with anyone other than me. I understand and accept that Dr. Janis and his staff will not discuss any aspect of my choices, decisions, requests, or result following surgery with anyone who was not educated, informed, or who did not answer all of the items in the second section of this document.**

_____ If I do not specify another person who will be involved, following surgery I accept total and complete responsibility for dealing with other peoples' opinions regarding my choices or my result. I will not involve anyone else in discussions with Dr. Janis or his staff following surgery regarding any aspect of my result if I did not specify and involve that person to assure that they are educated and informed prior to my surgery.

_____ If I choose to involve anyone else in my choices, decision-making, or in any evaluation or comment on my results, I will be personally responsible for providing that person a copy Dr. Janis' educational material, Dr. Janis' choices documents, informed consent documents, operative consent forms, and my breast implant manufacturer's information and operative consent forms. Further, I will encourage that person to read the documents in detail so that we reach a common understanding and acceptance of choices, risks, and tradeoffs prior to my surgery. Lastly, I will invite and encourage that person to participate in all of my consultations with my patient educator (in person or by phone) and in person for my consultation with Dr. Janis.

_____ **I understand and accept that I alone am ultimately responsible for the decisions I make and the requests that I make of Dr. Janis. If I involve anyone else in my decisions, it is my responsibility alone to reconcile their wishes and thoughts with what I choose for my own body. Dr. Janis will rely solely on my written requests that I will complete during my education and consultation process, and any other person's input must be included in my written requests prior to surgery. Prior to surgery, I alone am responsible for making my choices and decisions. Following surgery, I alone will accept responsibility for my choices and decisions, and I alone will discuss any concerns I have with Dr. Janis and his staff.**

Please ask the person you choose to involve in your choices or decision-making prior to your breast augmentation procedure to please complete and sign the document entitled **Will Anyone Else Be Involved – Part 2**. You are then responsible for returning the form to our office at least two weeks prior to your surgery date. **If you have specified a person to be involved, and this form is not returned to us at least two weeks prior to surgery, we will be unable to perform your surgery.**

_____ I have been given a copy of Will Anyone Else Be Involved- Part 2 and am aware that it must be returned to Dr. Janis' office two weeks prior to my surgery date.

Signed this _____ day of the month of _____, 2004 in the presence of the witness listed below.

Patient Signature

Witness Signature

Will Anyone Else Be Involved in Your Choices or Decision-Making? (Part 2)

Please ask the person you choose to involve in your choices or decision-making prior to your breast augmentation procedure to please complete and sign the following form. You are then responsible for returning the form to our office at least two weeks prior to your surgery date. If you have specified a person to be involved, and this form is not returned to us at least two weeks prior to surgery, we will be unable to perform your surgery.

The person I choose to involve my choices and decision making for breast augmentation is _____

Relationship: _____

Patient signature: _____ **Date:** _____

Witness: _____ **Date:** _____

We appreciate your involvement and support in our patient’s choices and decision-making process for breast augmentation. In order for you to become familiar with essential information regarding the many choices and decisions that we must make, you will need to carefully read and consider all of the information that we have provided our patient and which she will provide you. We strongly encourage you to attend consultation visits so that we all understand and agree on the patient’s choices and desires, and the inherent tradeoffs, limitations, and risks that are involved. Each patient has different tissues and tissue limitations and tradeoffs, and we individualize our decisions to try to achieve the best possible long-term results with the fewest risks and tradeoffs. Only by being involved can you thoroughly understand choices and decisions, and the reasons behind those decisions.

Please circle the appropriate choice and initial each line.

- _____ I have/ have not completely all information materials sent to the patient.
- _____ I have/ have not completely read Dr. Janis’ Patient Choices Document.
- _____ I have/ have not completely read Dr. Janis’ How Did We Do Informing You Document.
- _____ I have/ have not completely read Dr. Janis’ Operative Consent Forms.
- _____ I have/ have not completely read the breast implant manufacturer’s information and consent forms.
- _____ I understand and accept that any input I have into choices or decisions must be reconciled with the patient having surgery, and that Dr. Janis will only consider the specific written requests of the patient alone when making all surgical and implant choice decisions.

_____ I have absolutely no specific preferences or desires regarding any aspect of the patient’s surgery or implant choices, including implant size or type or desired breast size or appearance that are not clearly expressed on the Patient Choices Document and the How Did We Do Informing You Document listed above. I understand that Dr. Janis cannot read my mind or the patient’s mind, and that in order for our desires to be met, we must be totally honest and forthright in our written requests of Dr. Janis prior to surgery.

_____ I have been provided opportunities by Dr. Janis and his staff to read all informational materials, patient choice forms, and informed consent documents, and I understand and accept all risks, limitations, and patient choices as listed on these forms. I am satisfied that I have been provided all information necessary for me to understand and I am satisfied that Dr. Janis and his staff have satisfactorily answered all of my questions regarding breast augmentation. I am/am not totally comfortable with the choices made by the patient, _____, who is my _____ (relationship). I clearly understand that Dr. Janis does not wish to proceed with any surgery if I have any unsatisfied concerns or questions until those concerns are addressed and I become totally comfortable.

_____ If I am not totally comfortable with any of the above items, I have made my concerns known to Dr. Janis personally (or through notification of _____, a member of his staff, on _____ date.)

_____ Following surgery, I understand and accept that any criticism or disagreement that I may have regarding the results of surgery will be discussed by Dr. Janis or his staff only in terms of the **written choices made by the patient prior to surgery**. My input must be through the patient and must be expressed clearly on the documents listed above. I am totally comfortable that all of my concerns and input are expressed in the written choices made by the patient, and I will not express any concerns following surgery regarding breast size or appearance that are not clearly specified in the documents prior to surgery.

Signed this _____ day of the month of _____, 2004 in the presence of the witness listed below.

Patient Signature

Witness Signature

Jeffrey E. Janis, M.D. Augmentation Mammoplasty Clinical Evaluation

Patient Preferences, Objectives, Preparation, History, Limitations, Exam, Implant Selection

<p>Size: Pt. Desires: o Natural appearing breast o Unnatural, bulging upper breast o Proportionate to protect tissues o Very large</p> <p>Approximate Desired Cup _____ Requests specific cc's _____</p> <p>o Pt. chooses size o Pt. leaves size Choice to Dr. Janis</p> <p>Implant: o Round o Anatomic o Smooth o Textured o Saline o Silicone o Pt. leaves Type Choice to Dr. Janis</p> <p>Pocket Location: o PRP o RM o Dr. Janis to decide</p> <p>Incision Location: o IM o PA o AX o UMB o Pt. Leaves Incision Choice to Dr. Janis Pts. Initials _____</p>	<p>Capsular Contracture and Tissue Stretch Factors:</p> <p>o Implant choice may affect risk</p> <p>o Pt. accepts full responsibility for all costs (hospital and anesthesia) for any surgery necessary to treat any capsule or tissue stretch deformities and costs exceeding costs of original surgery.</p> <p style="text-align: right;">Pts. Initials _____</p>	<p>Discussed/Patient Accepts That:</p> <p>o The larger the implant, the more risks of sensory loss, tissue damage, and need for re-operations</p> <p style="text-align: right;">Pts. Initials _____</p>
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>Age _____</p> <p>Height _____ Wt. _____ lbs</p> <p>Frame: Sm Med Lrg</p> <p>Torso: o NI Wide Nr</p> <p>Gravida _____</p> <p>Para _____</p> <p>Bra Band Size: 32, 34, 36</p> <p>Breast Cup Size (Approx.) _____</p> <p>Prior to pregnancy _____</p> <p>Largest with preg _____</p> <p>Current Cup Size _____</p> <p>Desired Cup Size _____</p> <p>Previous Breast Disease: None</p> <p>Biopsies: o No o Yes</p> <p>Family Hx. Breast Cancer No Yes</p> <p>Mother Grandmother Aunt Maternal Paternal</p>	<p>Previous Mammograms: <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Date: _____</p> <p>Interpretation: <input type="checkbox"/> Normal <input type="checkbox"/> Other: _____</p> <p>Pertinent Medical History: <input type="checkbox"/> None</p> <p>Smoker: <input type="checkbox"/> No <input type="checkbox"/> Yes _____</p> <p>Allergies: <input type="checkbox"/> NKA</p> <p>Current Meds, Herbs, Vits: _____ _____</p> <p>Companion: _____</p> <p>Relation: _____</p>	<p>Specific Limitations Discussed with Patient:</p> <p><input type="checkbox"/> Your breasts will never match</p> <p><input type="checkbox"/> You may lose some or all sensation</p> <p><input type="checkbox"/> You may see or feel edges of your implant due to thin tissues</p> <p><input type="checkbox"/> ...You may require re-operations and additional costs in the future due to implant size requested, your tissue stretch characteristics or capsule you form</p> <p><input type="checkbox"/> ...We give no guarantee of cup size</p> <p><input type="checkbox"/> ...Any re-operation may require an inframammary incision</p> <p><input type="checkbox"/> Other: _____</p> <p><input type="checkbox"/> Patient vocalizes understanding and acceptance of all items checked</p>	<p style="text-align: center;">Breast Masses</p> <p><input type="checkbox"/> None <input type="checkbox"/> Size and Location: _____</p> <p>Larger Breast: <input type="checkbox"/> Left <input type="checkbox"/> Right</p> <p>Est. Vol. Diff. _____ cc TBD</p> <p>Nipple Level Discrepancy _____ cm N/A</p> <p>IMF Level Discrepancy _____ cm N/A</p> <p>Envelope Compliance <input type="checkbox"/> NI <input type="checkbox"/> Inc <input type="checkbox"/> Dec</p> <p><input type="checkbox"/> Constricted Lower Env. <input type="checkbox"/> Short, fixed IMF <input type="checkbox"/> Other: _____</p>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Clinical Breast Measurements L/R	<i>Estimating Desired Breast Implant Volume Based on Breast Measurements and Tissue Characteristics</i>											
	The modified TEPID System											
Base Width	Base Width Parenchyma (cm)	10.5	11.0	11.5	12.0	12.5	13.0	13.5	14.0	14.5	15.0	
	Estimated Initial Implant Volume (cc's)	200	250	275	300	300	325	350	375	375	400	
APSS _{MaxStr}	If APSS < 2.0, - 30cc											
	If APSS > 3.0, + 30cc											
	If APSS > 4.0, + 60cc											
N:IMF _{MaxSt}	If N:IMF > 9.5, + 30cc											
PCSEF	If PCSEF < 20%, + 30cc											
	If PCSEF > 80%, - 30cc											
IDFDD	If McGhan 468 implant, -30cc											
Pt. request												
	Total Estimated Implant Volume											
Estimating the Optimal Level of the Inframammary Fold Relative to the Nipple												
	For each volume indicated	200	250	275	300		325	350	375		400	
	Set new IMF at A:IMF distance (cm.) (measured under maximal stretch)	5.0	5.0	5.5	6		6	6.5	7.0		7	
	OR											
	Set new IMF at N:IMF distance (cm.) (measured under maximal stretch)	7.0	7.0	7.5	8		8.25	8.5	9.0		9.5	

SNN/N:IMF

R /
L /

R / L

BD /
APSS /
AD /
SPP /
IPP /
PP /
PCEF /
C:IMF /
U:IMF /
ChCirc /

Notes:

McGhan 68 MP			McGhan 468 Anatomic			Mentor HPS			Mentor Smooth Round			Mentor CPG		
Base	Proj	Vol	Base	Proj	Vol	Base	Proj	Vol	Base	Proj	Vol	Base	Proj	Vol.
10.2	3.4	180-210	10.0	4.0	195-205	10.0	4.3	230+45	9.5	3.0	125+25	10.0	3.7	155
10.6	3.7	210-240	10.5	4.2	230-240	10.2	4.5	250+50	10.0	3.1	150+25	10.5	3.8	180
11.1	3.8	240-270	11.0	4.3	270-285	10.4	4.6	270+55	10.6	3.3	175+25	11.0	3.9	215
11.6	3.9	270-300	11.5	4.6	300-315	10.8	4.7	290+60	11.0	3.4	200+25	11.5	4.0	245
11.9	4.1	300-330	12.0	4.8	350-370	11.0	4.8	310+65	11.5	3.5	225+25	12.0	4.2	280
12.3	4.2	330-360	12.5	4.9	380-400	11.3	4.8	330+70	11.9	3.6	250+25	12.5	4.4	315
12.7	4.2	360-390	13.0	5.3	450-475	11.7	5.2	380+70	12.3	3.7	275+25	13.0	4.4	355
13.0	4.5	390-420	13.5	5.5	495-520				12.6	3.7	300+25	13.5	4.7	395
			14.0	5.7	560-590				13.0	3.8	325+50	14.0	4.9	440
			14.5	5.9	620-650				13.6	4.0	375+50	14.5	5.0	480
			12.5	4.9	380-400				14.2	4.1	425+50	15.0	5.2	530
									14.8	4.2	475+50			

Surgeon Consultation Notes

Date: _____

Procedure(s) selected: *Augmentation Mammoplasty* (all options):

- | | |
|------------------------|---------------------------------------------|
| Transaxillary approach | Smooth, saline filled prosthesis |
| Inframammary approach | Textured, saline filled prosthesis |
| Periareolar approach | Textured, anatomic saline filled prosthesis |
| Umbilical approach | Other: _____ |

- Discussed in detail with patient all items on our information sheet regarding the procedure(s) listed above. I have given the patient detailed written information material to read and review, and have encouraged the patient to make a list of questions or items for clarification to be discussed prior to a surgical decision.
- Discussed with patient that this surgery is totally elective and not absolutely necessary. Emphasized alternatives available for treatment, including no treatment at all, with relative benefits, risks, and tradeoffs as described in the written information materials given to the patient.
- Emphasized to patient the possibility of complications including possible life threatening and deforming complications, and that if complications occur, additional time off work or normal activity and additional expenses will be incurred.
- Please make a second visit appointment with me if the patient desires after having thoroughly read all written information reiterating our initial discussion. At that visit we will review all items on information sheet and answer any questions.
- Scheduling and fees information per attached sheet.
- Letter to patient's referring source (Dictated).
- Letter to patient's insurance company (Dictated).

OTHER:

I reviewed with patient all items on the above listed information sheet(s), clarifying and answering all of the patient's questions.

- Preoperative photographs taken.
- Projected prosthetic and special instrument requirements: _____
- Short Stay Form or H&P completed.

Patient Images Analysis:
Factors Unlikely to Change or Permanently Corrected
Following Your Breast Augmentation

Patient: _____

Date: _____

- L/R breast larger- breasts will never match
- L/R nipple-areola higher on chest- will not be totally corrected
- L/R fold beneath breast higher on chest- will not be totally corrected
- Nipple position on the breast mounds is different on the two sides and cannot be totally corrected
- Gap between breasts can only be narrowed somewhat- a gap of at least _____cm. will likely remain
- Chest wall asymmetries exist that cannot be corrected and will affect breast shape
- The position of the entire breast on the chest wall will not change. If one fold beneath the breast is lower than the other, it will also be lower after your augmentation.
- The basic shape and configuration of the breasts will be similar to their current appearance and not change drastically, but will be larger

Other: _____

Other: _____

Other: _____

Other: _____

Other: _____

Please Initial below to document your understanding and acceptance of the above.

_____ Dr. Janis has reviewed my patient images with me in detail. I have seen, understand, and accept each of the factors listed above that will not change or may be only partially improved following my augmentation. I totally understand and accept that my breasts or components of my breasts will never match on the two sides, and that perfection is not an option, only improvement in the size of my breasts.

I certify this form has been fully explained to me, that I have read it or have had it read to me, that the blank spaces have been filled in, and that I understand its contents.

Signed this _____ day of the month of _____, 2004 in the presence of the witness listed below.

Patient Signature

Date

Witness Signature

Date

_____ I have been given a copy of this document for my personal records.

Disclosure and Consent for Augmentation Mammoplasty

You have the right, as our patient, to be informed about your condition and the recommended surgical, medical, or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the procedure.

I voluntarily request Dr. Janis as my physician, and such associates, technical assistants and other health care providers as they may deem necessary, to treat my condition which has been explained to me as:

Inadequate size of my breasts (Hypermastia)

I understand that the following surgical, medical, and/or diagnostic procedures are planned for me and I voluntarily consent and authorize these procedures:

Augmentation Mammoplasty- breast enlargement with breast implant

I understand that Dr. Janis may discover other or different conditions which require additional or different procedures than those planned. I authorize Dr. Janis, and such associates, technical assistants and other health care providers to perform such other procedures which are advisable in their professional judgment. I understand that no warranty or guarantee has been made to me regarding result or cure.

Just as there may be disadvantages in continuing my present condition without treatment, there are also risks and hazards related to the performance of the surgical, medical, and/or diagnostic procedures planned for me. I realize that common to surgical, medical, and/or diagnostic procedures is the potential for infection, blood clots in veins and lungs, hemorrhage, allergic reactions, and even death. I also realize that the following risks and hazards may occur in connection with this particular procedure:

- Postoperative infection
- Postoperative bleeding that may require drainage or Re-operation
- Pain or discomfort
- Removal or replacement of any implanted device or material
- Loss of skin over breasts
- Nipple numbness
- Extrusion of implant
- Increased risk of capsular contracture
- Unsatisfactory cosmetic result
- Prostheses will make mammograms more difficult to read
- The life of a breast implant is not known, replacement or removal (additional surgery) may be required
- Other risks, side effects, diseases or potential hazards as yet unsubstantiated
- Recurrence of Hematoma

I have read completely Dr. Janis' information sheets on augmentation mammoplasty. I understand all of the information contained in the sheets, and have had an opportunity to discuss and ask questions about this information. I have been given an opportunity to ask questions about my condition, alternative forms of treatment, risks of non-treatment, the procedures to be used, and the risks and hazards involved, and I believe that I have sufficient information to give this informed consent. I understand that this is an elective cosmetic procedure and is not reimbursable by Third Party payers.

I hereby give permission to Dr. Janis to take clinical photographs with the understanding that such photographs will remain the property of Dr. Janis. If in Dr. Janis' judgment, education, medical research, or surgical knowledge may be benefited by their use, then these photographs or related information may be published and republished in professional journals or medical books, or used for education or any other purpose which Dr. Janis may deem proper. It is specifically understood that in any such publications or use, I shall not be identified.

I certify this form has been fully explained to me, that I have read it or have had it read to me, that the blank spaces have been filled in, and that I understand its contents.

Signed this _____ day of the month of _____, 2004 in the presence of the witness listed below.

Patient Signature

Date

Witness Signature

Date

_____ I have been given a copy of this document for my personal records.

Verification of Informed Consent Regarding Breast Implants and Breast Augmentation Surgery

Please initial each blank indicating your complete understanding and acceptance of the information presented:

_____ Dr. Janis has provided me detailed, written information sheets which he has compiled regarding breast augmentation surgery. He has also provided me the manufacturer’s package insert for the type of implants I have selected, and also the website of the Food and Drug Administration (www.fda.gov) from whom I can seek additional information if I desire. I have read and thoroughly understand all of the information contained in Dr. Janis' information sheets as well as the manufacturer’s package insert materials regarding breast implants and breast implant surgery, and I have had an opportunity to discuss all of my areas of concern in detail with Dr. Janis and his staff prior to making a decision about having breast augmentation surgery.

_____ **I understand that a breast implant is a medical device, and I am comfortable that Dr. Janis has supplied me with all information pertaining to this device which is currently available, and has provided me with additional sources to seek information or verification of information with breast implants and breast implant surgery.**

_____ Having been given this information, having had an opportunity to discuss and ask any questions I desire regarding the information, and having had the opportunity to seek verification or additional information from other sources, I thoroughly understand the alternatives, risks, and limitations of breast implants and breast implant surgery. I accept these risks and limitations, understanding:

_____ 1) Life expectancy of a breast implant is not currently known, and I may require removal or replacement of my implant at some future time either as the result of medical necessity or my desire for a different or better implant.

_____ 2) Technology of breast implant design, development and manufacture will undoubtedly continue to progress and improve as it has in the past, and that implants which may be better in some way or another will inevitably be developed in the future.

_____ 3) Current scientific data does not clearly establish any definite cause and effect relationship between breast implants and cancer or other systemic diseases, but Dr. Janis has thoroughly informed me that he cannot absolutely assure me that there is not a remote possibility that a breast implant could cause or contribute to a systemic disease, though in over 25 years of use clinically in over 1 million patients such a link has not been clearly established.

_____ 4) All current breast implants interfere to some degree with mammographic examination of the breast and may affect early detection of breast cancer.

_____ 5) Breast cancer as well as other systemic diseases such as connective tissue disorders, scleroderma, rheumatoid arthritis, and numerous other diseases occur in the normal adult female population with a certain frequency, whether a woman has breast implants or not, and I understand that I may develop breast cancer or another of these diseases after having breast implants simply because I am a woman and not because of the implants.

_____ 6) Also, because bra cup size is such a variable depending on bra type, manufacturer, and my own personal preferences regarding the fit of a bra that Dr. Janis has clearly discussed with me and I understand that he cannot guarantee any specific bra cup size or result. After our discussions and consultation, I am comfortable that Dr. Janis understands my wishes regarding my breasts and I have requested that he use his best medical and aesthetic judgment in determining the best appearance for my breasts.

_____ I thoroughly understand all of the above information which has been given me, I have had an opportunity to discuss it or ask additional questions to any degree required for my satisfaction, I understand and accept any risks which may be associated with breast implants or breast implant surgery, and request that Dr. Janis precede with my augmentation mammoplasty.

I certify this form has been fully explained to me, that I have read it or have had it read to me, and that I understand and accept its contents.

Signed this _____ day of the month of _____, 2004 in the presence of the witness listed below.

Patient Signature

Date

Witness Signature

Date

_____ I have been given a copy of this document for my personal records.