

Informed Consent

Breast Implant Removal

INSTRUCTIONS

This is an informed consent document that has been prepared to help inform you about breast implant removal surgery, its risks, and alternative treatment(s).

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page, and sign the consent for surgery as proposed by your plastic surgeon and agreed upon by you.

GENERAL INFORMATION

The removal of breast implants that have been placed either for cosmetic or reconstructive purposes is a surgical operation. Breast implant removal may be performed as a single surgical procedure or combined with additional procedures, as follows:

- Simple breast implant removal, without removal of capsule tissue around implant
- Removal of tissue surrounding the breast implant (capsulectomy)
- Removal of escaped silicone gel in breast tissue (extracapsular, outside of capsule layer) from silicone gel-filled implants (breast biopsy)
- Breast lift (mastopexy following breast implant and/or capsule removal)

Implants that are found to be damaged or ruptured cannot be repaired; surgical removal or replacement is recommended. There are options concerning general versus local anesthesia for breast implant removal.

There are both risks and complications associated with this operation.

Individuals who choose to have revisions made in order to continue with breast implants must sign other consent documents for revision surgery. This document is intended for the permanent removal of breast implants and/or capsule material that surrounds the implants, or breast biopsy to remove silicone gel from outside of the capsule layer.

Individuals who choose to undergo a breast lift (mastopexy) at the time of breast implant removal must sign an additional informed consent document for the breast lift (mastopexy).

ALTERNATIVE TREATMENTS

Alternative forms of non-surgical management include not undergoing breast implant removal, or other procedures to replace, relocate, or revise existing situations when patients choose to continue with breast implants. Risks and potential complications are associated with alternative surgical forms of treatment.

INHERENT RISKS OF BREAST IMPLANT REMOVAL SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand all of the possible consequences of breast implant removal surgery.

SPECIFIC RISKS OF BREAST IMPLANT REMOVAL SURGERY

Skin Wrinkling and Rippling:

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

Ruptured Silicone Gel-Filled Breast Implants:

As with any manmade object implanted in the human body, device failure can occur. It is possible that an implant can rupture causing silicone gel to be released from the implant. Implants also can rupture during the removal process. If implant rupture has occurred, it may not be possible to completely remove all of the silicone gel that has escaped. The implant shell material of textured breast implants may be impossible to remove completely. Calcification around implants can occur and may require removal of the scar tissue surrounding the implant (capsulectomy). It may not be possible to completely remove the scar tissue that has formed around a breast implant, implant parts, calcifications, or silicone gel. Additional surgery may be necessary in the future.

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Delayed Healing and Tissue Necrosis:

Wound disruption or delayed wound healing is possible. Some areas of the breast skin or nipple region may not heal normally and may take a long time to heal. Areas of skin or nipple tissue may die. Tissue death (necrosis) can potentially occur when surgery is performed to remove implants, capsule tissue, and procedures to tighten the skin and move the nipples upward (mastopexy). Necrosis has also been reported with the use of steroid drugs, after chemotherapy/radiation to breast tissue, and due to smoking, microwave diathermy, and excessive heat or cold therapy. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Individuals who have decreased blood supply to breast tissue from past surgery or radiation therapy may be at increased risk for delayed wound healing and poor surgical outcomes. Smokers have a greater risk of skin loss and wound healing complications.

Change in Nipple and Skin Sensation:

You may experience a diminished (or loss of) sensitivity of the nipples and the skin of your breast that usually resolves in three to four weeks. Partial or permanent loss of the nipple and skin sensation is rare. However, decreased or permanent loss in nipple sensation is more likely to occur if extensive surgical dissection is needed to remove scar tissue or silicone gel from a broken implant.

Skin Contour Irregularities:

Contour and shape irregularities may occur. Visible and palpable wrinkling may occur. One breast may be smaller than the other. Nipple position and shape will not be identical on each side. Residual skin irregularities at the ends of the incisions or "dog ears" are always a possibility when there is excessive redundant skin. This may improve with time, or it can be surgically corrected.

Breast Disease:

Current medical information does not demonstrate an increased risk of breast cancer in women who have breast implant surgery for either cosmetic or reconstructive purposes. Individuals with a personal history or family history of breast cancer may be at a higher risk of developing breast cancer than a woman with no family history of this disease. It is recommended that all women perform periodic self-examination of their breasts, undergo routine mammography according to American Cancer Society guidelines, and seek professional care should a breast lump be detected. In the event that suspicious tissue is identified prior to or during breast surgery, additional tests and therapy with corresponding expenses may be warranted.

GENERAL RISKS OF SURGERY

Healing Issues:

Certain medical conditions, dietary supplements, and medications may delay and interfere with healing. Patients with massive weight loss may have a healing delay that could result in the incisions coming apart, infection, and tissue changes requiring additional medical care, surgery, and prolonged hospitalizations. Patients with diabetes or those taking medications such as steroids on an extended basis may have prolonged healing issues. Smoking will cause a delay in the healing process, often resulting in the need for additional surgery. There are general risks associated with healing such as swelling, bleeding, possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, unmet patient goals and expectations, and added expense to the patient. There may also be a longer recovery owing to the length of surgery and anesthesia. Patients with significant skin laxity (patients seeking facelifts, breast lifts, abdominoplasty, and body lifts) will continue to have the same lax skin after surgery. The quality or elasticity of skin will not change and recurrence of skin looseness will occur at some time in the future, more quickly for some than for others. There are nerve endings that may be affected by healing scars from procedures such as suction-assisted lipectomy, abdominoplasty, facelifts, body lifts, and extremity surgery. While there may not be a major nerve injury, the small nerve endings may become too active during the healing period, producing a painful or oversensitive area due to the small sensory nerves involved with scar tissue. Often, massage and early non-surgical interventions resolve this. It is important to discuss postsurgical pain with your surgeon.

Bleeding:

It is possible, though unusual, to experience a bleeding episode during or after surgery. Should postoperative bleeding occur, it may require emergency treatment to drain accumulated blood or you may require a blood transfusion, though such occurrences are rare. The collection of blood that can occur under your skin following surgery is referred to as a hematoma. Increased activity too soon after surgery can lead to an increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and to limit exercise and strenuous activity for the instructed time period. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. Hematoma can occur at any

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time, usually in the first three weeks following injury to the operated area. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS). Your surgeon may provide medications after your surgery to prevent blood clots. Medications that are used to prevent blood clots in veins can result in bleeding and decreased blood platelets.

Infection:

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

Ileus:

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

Scarring:

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

Firmness:

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

Skin Sensitivity:

Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. Usually this resolves during healing, but in rare situations, it may be chronic.

Major Wound Separation:

Wounds may separate after surgery. Should this occur, additional treatment including surgery may be necessary.

Sutures:

Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible, or produce irritation that requires suture removal.

Damage to Deeper Structures:

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

Fat Necrosis:

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

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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.

Shock:

In rare circumstances, your surgical procedure may cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment will be necessary.

Pain:

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

There are nerve endings that may be affected by healing scars from surgery. While there may not be a major nerve injury, small nerve endings may become too active during the healing period, producing a painful or oversensitive area due to the small sensory nerves involved with scar tissue. Often, massage and early non-surgical interventions resolve this. It is important to discuss postsurgical pain with your surgeon.

Cardiac and Pulmonary Complications:

Pulmonary complications may occur secondarily to blood clots (pulmonary emboli), fat deposits (fat emboli), pneumonia, or partial collapse of the lungs after general anesthesia. Pulmonary emboli can be life threatening or fatal in some circumstances. Inactivity and other conditions may increase the incidence of blood clots traveling to the lungs and causing a major blood clot that may result in death. It is important to discuss any past history of swelling in your legs or blood clots that may contribute to this condition with your physician. Cardiac complications are a risk with any surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heartbeats, seek immediate medical attention. Should any of these complications occur, hospitalization and additional treatment may be required.

Venous Thrombosis (Clot) and Sequelae:

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

Allergic Reactions:

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

Drug Reactions:

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

Asymmetry:

Symmetrical body appearance may not result after surgery. Factors such as skin tone, fatty deposits, skeletal prominence, and muscle tone may contribute to the normal asymmetry of body features. Most patients have differences between the right and left sides of their bodies before any surgery is performed. Additional surgery may be necessary to attempt to diminish asymmetry.

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Surgical Wetting Solutions:

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

Fat/Air Embolism:

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

Persistent Swelling (Lymphedema):

Persistent swelling can occur following surgery.

Unsatisfactory Results:

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

ADDITIONAL ADVISORIES

Medications and Herbal Dietary Supplements:

Potential adverse reactions may occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with the formation of blood clots, and therefore may contribute to bleeding issues. If you have a medical condition (such as heart arrhythmia, heart stent, blood vessels with blockages, or blood clots) and are taking medications to thin your blood and prevent clotting such as Plavix®, Coumadin®, Xarelto®, Effient®, or Pradaxa®, you should discuss management of these medications around the time of the surgery with your plastic surgeon. Your plastic surgeon may opt to coordinate a plan for these medications with the doctor that prescribed them for your medical condition. If you have been prescribed drugs for a medical condition, do not stop taking them without discussing it first with your plastic surgeon. Stopping these medications abruptly may result in a heart attack, stroke, or death. Be sure to check with your physician about any drug interactions that may exist with the medications that you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room.

When taking the prescribed pain medications after surgery, be aware that they can affect your thought processes and coordination. Do not drive, do not operate complex equipment, do not make any important decisions, and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

Sun Exposure – Direct or Tanning Salon:

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

Travel Plans:

Any surgery carries the risk of complications that may delay healing and your return to normal life. Please let the surgeon know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that the appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired timeframe. Allow at least 10-14 days to travel via airplane. Medications may be required should you have a long flight/trip in order to prevent DVT/PE in the immediate postoperative period.

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Long-term Results:

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

Interference with Sentinel Lymph Node Mapping Procedures:

Breast surgery procedures that involve cutting through breast tissue, similar to a breast biopsy, can potentially interfere with diagnostic procedures to determine the lymph node drainage of the breast tissue in the staging of breast cancer.

Body-Piercing:

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

Future Pregnancy and Breastfeeding:

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

Female Patient Information:

It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

Intimate Relations after Surgery:

Since surgery involves the coagulation of blood vessels, increased activity of any kind may open these vessels leading to bleeding or hematoma. Activities that increase your pulse or heart rate may cause additional bruising, swelling, and the need for additional surgery to control bleeding. It is wise to refrain from intimate physical activities until your physician states it is safe.

Mental Health Disorders and Elective Surgery:

It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery, and are often stressful. Prior to surgery, please openly discuss any history that you may have of significant emotional depression or mental health disorders with your surgeon. Although many individuals may benefit psychologically from the results of elective surgery, its effects on mental health cannot be accurately predicted.

ADDITIONAL SURGERY NECESSARY (Re-Operations)

Many variable conditions may influence the long-term results of surgery. It is unknown how your tissue may respond or how wound healing will occur after surgery. Secondary surgery may be necessary to perform additional tightening or repositioning of body structures. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are associated with this surgery. Other complications and risks can occur but are less common. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty, expressed or implied, as to the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. You and your surgeon will discuss the available options should additional surgery be advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, pathology, and lab testing.

PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are <u>not</u> subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activities need to be restricted. Protective dressings and drains should <u>not</u> be removed unless instructed by your plastic surgeon. Successful postoperative function depends on both the surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for additional surgery. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

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ATTESTATIONS

Smoking, Second-hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray):

Patients who are currently smoking or using tobacco or nicotine products (patch, gum, or nasal spray) are at greater risk for significant surgical complications, such as skin loss, delayed healing, and additional scarring. Individuals exposed to secondhand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of these types of complications. Please indicate your current status regarding these items below:

I am a non-smoker and do not use nicotine products. I understand the potential risk of secondhand smoke exposure causing surgical complications.
I am a smoker or use tobacco/nicotine products. I understand the risk of surgical complications due to smoking or the use of nicotine products.
I have smoked and stopped approximately ago. I understand I may still have the effects and therefore the risks of smoking in my system, if not enough time has elapsed.
I have been advised to stop smoking immediately and have been informed of the risks, benefits, expectations, and alternatives to my surgery if I continue smoking.

It is important to refrain from smoking at least four weeks before surgery and until your physician states it is safe to return, if desired. I acknowledge that I will inform my physician if I continue to smoke within this timeframe, and I understand that for my safety, the surgery, if possible, may be delayed.

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

DISCLAIMER

Informed consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with the disclosure of risks and alternative forms of treatment(s), including no surgery. The informed consent process attempts to define the principles of risk disclosure that should meet the needs of most patients in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information that is based on all the facts of your particular case and the current state of medical knowledge.

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

It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

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CONSENT for SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize <u>Dr. David Deisher / Dr. Stewart Humphrey</u> and such assistants as may be selected to perform **Breast Implant Removal Surgery.**

I have received the following information sheet: Breast Implant Removal Surgery.

- 2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those described above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are necessary and desirable in the exercise of his or her professional judgment. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
- 3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
- 4. I understand what my surgeon can and cannot do, and understand there are no warranties or guarantees, implied or specific, as to my outcome. I have had the opportunity to explain my goals and I understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
- 5. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific, or educational purposes, provided my identity is not revealed by the pictures.
- 6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
- 7. I consent to the disposal of any tissue, medical devices, or body parts that may be removed.
- 8. I am aware that there are potential significant risks to my health with the utilization of blood products, and I consent to their utilization should they be deemed necessary by my surgeon and/or his/her appointees.
- 9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical device registration, if applicable.
- 10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
- 11. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
 - a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
 - b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
 - c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TRI I AM SATISFIED WITH T	ATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12). IE EXPLANATION.	
Patient or Person Authori	ed to Sign for Patient	_
Date/Time	Witness	

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