

# BOICE-WILLIS CLINIC, PA

Patient Name: \_\_\_\_\_ DOB: \_\_\_\_\_ MRN: \_\_\_\_\_



## Informed Consent

### Kybella® - Deoxycholic Acid Injection

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### **INSTRUCTIONS**

This is an informed consent document that has been prepared to help inform you about deoxycholic acid injection therapy, its risks, and alternative treatments.

This consent covers injection using:

\_\_\_ **Kybella®** - Deoxycholic acid is a man-made substance that assists with fat absorption. It destroys fat cells when injected into the body.

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 form for this procedure as proposed by your plastic surgeon and agreed upon by you.

### **GENERAL INFORMATION**

This injection will utilize a deoxycholic acid to improve the appearance of moderate to severe convexity or fullness associated with submental fat in adults. Deoxycholic acid has been FDA approved for cosmetic treatment of moderate to severe fullness in the area under the chin.

Injections are customized to each patient, depending on his or her particular needs. They are not designed to stop the process of aging. They can, however, temporarily diminish the look of fullness in the area under the chin.

These injections may be performed as a singular procedure, in combination with other treatments such as botulism toxins, or as an adjunct to a surgical procedure.

Multiple treatments may be necessary in order to produce the desired effect of deoxycholic injections.

### **ALTERNATIVE TREATMENTS**

Alternative forms of management include not treating the “double chin” by any means. Improvement of an excessive deposit of fat under the chin may be accomplished by other treatments: submental liposuction, submental liposuction, platysma plication, and facelift. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

### **INHERENT RISKS OF DEOXYCHOLIC ACID INJECTIONS**

Every 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 this procedure is should be based on a comparison between the risks and the potential benefits. Although the majority of patients do not experience the following, you should discuss each with your physician to make sure you understand the risks, potential complications, limitations, and consequences of deoxycholic acid injections. Additional information may be obtained from the package-insert sheets supplied by the manufacturers.

### **SPECIFIC RISKS OF DEOXYCHOLIC INJECTIONS**

#### **Bleeding and Bruising:**

It is possible, though unusual, to have a bleeding episode from a Kybella® injection or local anesthesia used during the procedure. Injury to the blood supply and bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, vitamin E, ginkgo biloba, and other “herbs/homeopathic remedies” may contribute to a greater risk of a bleeding problem. Do not take any of these for seven days before or after filler injections.

#### **Swelling:**

Swelling (edema) is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary.

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**Pain:**

Discomfort associated with injections is normal and usually of short duration. Pain and tenderness are expected after treatment, and should not last longer than 7 days. Please consult your physician regarding pain management.

**Numbness:**

Numbness around the injection area may occur. This is temporary and should resolve within a few days.

**Dysphagia:**

On rare occasions, difficulty swallowing may occur. Cases of dysphagia should resolve within 1-81 days.

**Facial Nerve Damage:**

Although rare, nerves around the treatment area may be affected by the injection, resulting in muscle weakness. Nerve injuries should resolve within a few days but may take up to 1 year to improve.

**Skin Hardness in Treatment Area:**

On rare occasions, skin hardness may occur in the treatment area. This is temporary and should resolve within a few days.

**Destruction of Skin Cells if Injected into Skin:**

Kybella® can destroy skin cells, if inadvertently injected into the skin.

**Needle Marks:**

Visible needle marks from the injections normally occur and resolve within a few days.

**Skin Sensitivity:**

Skin rash, itching, tenderness, and swelling may occur following injections. After treatment, you should minimize exposure of the treated area to excessive sun or UV lamp exposure and extreme cold weather conditions until any initial swelling or redness has gone away.

**Erythema (Skin Redness):**

Erythema in the skin occurs after injections. It can be present for a few days after the procedure.

**Infection:**

Although infection following Kybella® injection is unusual, bacterial, fungal, and viral infections can occur. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

**Asymmetry:**

The human face is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry following Kybella® injections. There can be variation between one side of the face to the other in terms of response to injection. This may require additional injections.

**Skin Necrosis:**

It is very unusual to experience loss of skin and deeper soft tissues after Kybella® injections. Skin loss can produce unacceptable scarring. Should this complication occur, additional treatments, or surgery may be necessary.

**Allergic Reactions and Hypersensitivity:**

Allergic and systemic anaphylactic reactions may occur. Deoxycholic acid injections should not be used in patients with a history of multiple severe allergies, severe allergies manifested by a history of anaphylaxis, or allergies to gram-positive bacterial proteins. Severe allergic reactions are rare but may occur. Allergic reactions may require additional treatment.

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**Unsatisfactory Result:**

Kybella® injections alone may not produce an outcome that meets your expectations for improvement in treatment of under chin fullness. There is a possibility of a poor or inadequate response to the injection(s). Additional injections may be necessary. Surgical procedures or other treatments may be recommended along with additional treatments. Unsatisfactory results may NOT improve with each additional treatment.

**Unknown Risks:**

The long-term effects of deoxycholic acid are unknown. The possibility of additional risk factors or complications attributable to the use of Kybella® may be discovered.

**Pregnancy and Nursing Mothers:**

Animal reproduction studies have not yet been performed to determine if deoxycholic acid could produce fetal harm. Risk of major birth defects and miscarriage is unknown. It is not known if Kybella® or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive deoxycholic acid injection treatments.

**Drug Interactions:**

It is not known if deoxycholic acid reacts with other drugs within the body.

**Long-term Effects:**

Deoxycholic acid injections should not be considered as a permanent treatment for the correction of submental fullness. Subsequent alterations in facial appearance may occur as a result of aging, weight loss or gain, sun exposure, or other circumstances not related to Kybella® injections. Deoxycholic acid injection does not arrest the aging process. Future surgery or other treatments may be necessary.

**Additional Treatment Necessary:**

There are many variable conditions in addition to risks and potential complications that may influence the long-term result of deoxycholic acid injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with Kybella® injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional treatments may be necessary. 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, regarding the results that may be obtained.

**GENERAL RISKS OF SURGERY**

**Healing Issues:**

Certain medical conditions, dietary supplements, and medications may delay or interfere with healing. Patients with massive weight loss may experience a delay in healing that could result in the incisions coming apart, infection, and tissue changes resulting in the need for 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 treatment. There are general risks associated with healing such as swelling, bleeding, possibility of additional procedures, prolonged recovery, color changes, shape changes, infection, not meeting patient goals and expectations, and added expense to the patient. While there may not be a major nerve injury, the small nerve endings during the healing period may become too active producing a painful or oversensitive area due to the small sensory nerves involved with scar tissue. Often, massage therapy and early non-surgical intervention resolves this. It is important to discuss post-surgical pain with your surgeon.

**Bleeding:**

It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain the accumulated blood or you may require a blood transfusion, though such occurrences are rare. The collection of blood that can occur under

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your skin following surgery is referred to as a hematoma. Increased activity too soon after surgery can lead to an increased risk of bleeding and additional surgery. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time. Non-prescription “herbs” and dietary supplements can increase the risk of surgical bleeding. Hematoma can occur at any time, usually in the first three weeks following injury to the operative area. If blood transfusions are necessary to treat blood loss, there is a 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 cause 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, open wounds, recent upper respiratory infections/pneumonia, ingrown toenails, insect bites, tooth abscesses, or urinary tract infections. Infections in other parts of the body, may lead to an infection in the operated area. Post-operative infections often result in more extensive scarring and can 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 hypomobility of your bowels/gut resulting in a lack of defecation and possibly repeated vomiting. Anesthetics and medications like pain medications given to you at the time of surgery can contribute to the development of an ileus in the post-operative 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 have 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 scarring may occur within the skin and deeper tissues. Scars may be unattractive and of 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 side of the body). There is also a 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 treatment. Usually this resolves during healing, but in rare situations, it may be chronic.

**Delayed Healing:**

Wound disruption or delayed wound healing is possible. Some areas of the skin may not heal normally and may take a long time to heal. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Individuals who have decreased blood supply to tissue from past surgery or radiation therapy may be at increased risk for wound healing and poor outcomes. Smokers have a greater risk of skin loss and wound healing complications.

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**Damage to Deeper Structures:**

There is a 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 a possibility of contour irregularities in the skin that may result from fat necrosis.

**Surgical Anesthesia:**

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

**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 in regular contact with 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 post-operative period. On rare occasions, chronic pain may occur from nerves becoming trapped in scar tissue or due to tissue stretching.

Certain nerve endings may become involved in healing scars from surgery. While there may not be a major nerve injury, the small nerve endings during the healing period may become too active producing a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often, massage therapy and early non-surgical intervention resolves this. It is important to discuss post-surgical pain with your surgeon.

**Cardiac and Pulmonary Complications:**

Pulmonary complications may occur secondary 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 migrating to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any past history of swelling in your legs or blood clots that may contribute to this condition. Cardiac complications are a risk associated with any anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heartbeats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

**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 with your surgeon any birth control pills you are taking. Certain high estrogen pills may increase your risk of thrombosed veins. A personal history of bleeding and clotting problems may also increase your risk of thrombosed veins.

**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 the procedure and prescription medicines. 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

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medication or allergies to medication, prescribed or over the counter, as well as medications you currently take regularly. Provide your surgeon with a list of medications and supplements you are currently taking.

**Persistent Swelling (Lymphedema):**

Persistent swelling can occur.

**Unsatisfactory Result:**

Although good results are expected, there is no guarantee or warranty expressed or implied, regarding the results that may be obtained. The body is not symmetrical and almost everyone has some degree of unevenness, which may not be recognized in advance. One side of the face may be slightly larger, one side of the face droopier. Many of such issues cannot be fully corrected with surgery. The more realistic your expectations are, the better your results will appear to you. Some patients never achieve their desired goals or results, at no fault of the surgeon or the surgery. You may be disappointed with the results of this procedure. Asymmetry, wound disruption, poor healing, and loss of sensation may occur. Unsatisfactory surgical scar location or appearance may occur. It may be necessary to perform additional injections to improve your results. Unsatisfactory results may NOT improve with each additional treatment.

**ADDITIONAL ADVISORIES**

**Medications and Herbal Dietary Supplements:**

There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with blood clot formation, and therefore may contribute to more 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®, discuss the management of these medications around the time of the procedure with your plastic surgeon. Your plastic surgeon may sometimes 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 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 any medications 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. 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 sun 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 holds 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 procedure can be timed accordingly. 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.

**Long-term Results:**

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

**Body Piercing:**

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

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**Jewelry:**

Jewelry should not be brought with you at the time of your procedure. Items, such as earrings, wedding rings, and necklaces should be removed and placed in a safe place.

**Female Patient Information:**

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

**Mental Health Disorders and Elective Procedures:**

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

**ADDITIONAL PROCEDURES NECESSARY**

There are many variable conditions that may influence the long-term result of this procedure. It is unknown how your tissue may respond or how wounds will heal. Should complications occur, additional treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are associated with this procedure. 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, on the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single procedure. You and your surgeon will discuss the options available should additional treatment 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. Personal and vocational activity may need to be restricted. Protective dressings should not be removed unless instructed by your plastic surgeon. Physical activity that increases your pulse or heart rate may cause bruising, swelling, or fluid accumulation. 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 use tobacco or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications such as skin loss and delayed healing and additional scarring. Individuals exposed to second-hand 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 the items below:

I am a non-smoker and do not use nicotine products. I understand the potential risk of second-hand smoke exposure causing procedural complications.

I am a smoker or use tobacco/nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

I have smoked and stopped approximately \_\_\_\_\_ ago. I understand I may still have the effects and therefore risks from smoking in my system, if not enough time has lapsed.

I have been advised to stop smoking immediately and have been informed of the risks, benefits, expectations, and alternatives to my treatment if I continue smoking.

It is important to refrain from smoking for at least 6 weeks before treatment 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 procedure, if possible, may be delayed.

Smoking may have such a negative effect on your procedure that a urine or blood test just before treatment may be done which will prove the presence of Nicotine. If positive, your procedure may be cancelled and scheduling fees, and other prepaid amounts may be forfeited. Honestly disclose your smoking habits with your surgeon.

**COMMUNICATION ACKNOWLEDGEMENT – CONSENT**

There are many ways to communicate with you. It is important to keep appointments and let us know if problems or issues arise. Methods of communication include telephone, text, pager, answering service if available, email, and regular mail. If an emergency arises, keep us alerted to your progress so we may aid in any necessary treatments. Please do not leave a message after hours or on weekends on the office answering machine if any urgent or emergent situation exists, as there will be a delay in retrieving such messages. All attempts will be made to preserve your privacy in accordance with HIPAA rules.

Please confirm below all acceptable ways of communicating with you:

Telephone  
 Home ( - - )  
 Work ( - - )  
 Cell ( - - )  
 Text  
 Pager – Answering Service if available  
 Email – with up to date email address ( @ )  
 Regular Mail and Delivery

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**DISCLAIMER**

Informed consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including a decision not to proceed with surgery. This document is based on a thorough evaluation of scientific literature and relevant clinical practices to describe a range of generally acceptable risks and alternative forms of management of a particular disease or condition. The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information, which is based on all the facts in 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 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 Karen Szymanski, DO, MPT and assistants that may be selected to perform Kybella® - Deoxycholic Acid Injection.

I have received the following information sheet: Kybella® - Deoxycholic Acid Injection.

- 2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. 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, regarding my outcome. I have had the opportunity to explain my goals and 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 being 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 procedure room.
7. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
8. 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.
9. I realize that not having the operation is an option. I opt out of having this procedure \_\_\_\_\_.
10. 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 TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-10). I AM SATISFIED WITH THE EXPLANATION.

\_\_\_\_\_  
Patient or Person Authorized to Sign for Patient

Date/Time \_\_\_\_\_ Witness \_\_\_\_\_