

# **Informed Consent**

**Tenolysis Surgery** 

# **INSTRUCTIONS**

This is an informed-consent document that has been prepared to help inform you about tenolysis surgery, its risks, as well as 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**

Tendons connect muscles in the forearm to structures within the hand and fingers. Tendons allow the contractile force of forearm muscles to be used for movement in the wrist, hand, and fingers. Tendon scarring may occur from cuts, injuries, surgery, or infections. Tendons can be injured by attritional changes in arthritic conditions. Scarring may severely affect function of the hand due to limitation of tendon movement and the development of joint stiffness.

Restoration of hand function after tendon scarring has developed requires surgery to release the trapped tendon(s), aftercare, and supervised hand rehabilitation in order to obtain the best results.

#### **ALTERNATIVE TREATMENTS**

Alternative forms of care consist of not undergoing surgery. In some situations, tendon function may be restored with hand therapy.

#### **INHERENT RISKS OF TENOLYSIS 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 possible consequences of tenolysis surgery.

#### SPECIFIC RISKS OF TENOLYSIS SURGERY

#### **Recurrent Tendon Scarring:**

Scarring can recur around the tendon(s) or in nearby structures and prevent the return of normal tendon function. Surgery may or may not be successful in freeing the tendon from scar tissue which impairs motion.

#### **Inability to Restore Function:**

Tendon scarring often involves more than just the tendon. Other structures, such as joints may lose normal motion. Not all damaged structures can be surgically treated. Injuries to other soft tissues and bone may prevent adequate tendon function despite a successful tenolysis. Some hand disorders may be so severe that there is no reasonable expectation of return of function. Complications involving other parts of the hand and forearm may occur.

# **Stiffness of the Joints:**

You may experience difficulty moving a joint or the apparent loss of range of motion of a joint, after the surgery. Joint redness, tenderness, warmth, tingling, or numbness of an affected area of the body may be present.

#### **Complex Regional Pain Syndrome (CRPS):**

In rare cases, complex regional pain syndrome may develop after the surgery. You may experience pain, swelling, redness, noticeable changes in temperature and hypersensitivity, which are signs of CRPS. In

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some people, signs and symptoms of complex regional pain syndrome often go away on their own. In others, they may persist, and require further treatment.

# **Change in Skin Sensation:**

A diminished (or loss of) skin sensitivity in the finger, hand or forearm may occur and not totally resolve after tenolysis surgery.

#### **Rupture of Tendon:**

It is possible that a tendon(s) can break apart following tenolysis surgery. Breakage of a tendon is a serious problem. If breakage occurs, additional surgery would be necessary to secondarily repair or graft the ruptured tendon. It is important that you follow all post-operative instructions concerning the avoidance of tendon damage.

## <u>Damage to Associated Structures:</u>

Structures such as nerves, blood vessels, bones and soft tissues may be damaged during surgery. The potential for this to occur varies with the type of surgical technique utilized. Additional surgery may be necessary should this problem occur. Injury to associated structures may be temporary or permanent.

# **Wound Breakdown:**

It is possible that the incisions used to perform the tenolysis can break open, exposing the tendon(s). Wound disruption following tenolysis surgery can produce a poor surgical result. If this occurs, additional treatment may be necessary.

## **Additional Incisions Necessary:**

It may be necessary to extend the original wound where tendon scarring occurs or make new incisions to release scar tissue that is limiting tendon motion.

#### **Abnormal Tendon Position:**

Tenolysis surgery can disrupt the tendon sheath and its pulley system. If this occurs, the tendon may assume an abnormal position that may interfere with function. It may not be possible to correct this problem if it occurs.

# **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 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 surgery. There are general risks associated with healing such as swelling, bleeding, possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, not meeting patient goals and expectations, and added expense to the patient. There may also be a longer recovery due to the length of surgery and anesthesia. There are nerve endings that may become involved with healing scars from extremity 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 nerves involved with scar tissue. Often, massage 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 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

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under your skin following surgery is referred to as a hematoma. Increased activity too soon after surgery can lead to increased chance 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 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 produce 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 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. Post-operative infections often result in more extensive scarring and predispose to revision surgery.

#### **Ileus:**

The return of bowel function following surgery is important. An ileus are disruptions 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 an aspiration pneumonia and respiratory failure. It can be 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 scars 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 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.

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# **Damage to Deeper Structures:**

There is the potential for injury to deeper structures including nerves, blood vessels, lymphatics, muscles, and bone or joint structures 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 to the skin might die. This may produce areas of firmness under the skin. Additional surgery to remove areas of fat necrosis may be necessary. There is the possibility of contour irregularities in the skin that may result from fat necrosis.

## **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 can 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 would 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 post-operative period. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

There are nerve endings that may become involved with 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 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 traveling 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 with any surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heart beats, 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. Personal history of bleeding and clotting problems may also increase your risk of thrombosed veins.

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

# **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 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 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 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, one side of the face droopier. The breast and trunk area exhibits the same possibilities. Many of such issues cannot be fully corrected with surgery. The more realistic your expectations as to 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:**

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 normal platelet function, 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, Warfarin, Coumadin, Xarelto, Effient or Pradaxa, discuss management of these medications around the time of surgery 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 medications which you are already taking. If you have an adverse reaction, stop the drugs

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#### 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, realize that they can affect your thought process 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.

# <u>Sun Exposure – Direct or Tanning Salon</u>:

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 appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame. Allow at least 10-14 days to travel via airplane. Medications may be required should you have a long flight/ trip to prevent DVT/ PE in the immediate post-operative period.

#### **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 <u>not</u> 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 lymph node drainage of breast tissue to stage 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.

#### Nails:

To monitor your vital signs during surgery, your anesthesia provider may require access to your finger nails for monitoring. Make sure to have at least two finger nails free of nail polish or acrylic nails on the date of your surgery.

#### Jewelry:

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

#### **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.

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# **Intimate Relations After Surgery**:

Surgery involves coagulating of blood vessels and increased activity of any kind may open these vessels leading to a bleed, or hematoma. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need for return to 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 often are stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

#### **ADDITIONAL SURGERY NECESSARY (Re-Operations):**

There are many variable conditions that may influence the long-term result 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, on 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 options available 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 activity needs to be restricted. Protective dressings and drains should <u>not</u> be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bleeding, bruising, swelling, fluid accumulation and the need for return to surgery. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

#### **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 of 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 type of complications. Please indicate your current status regarding these items below:

Informed Consent – Tenolysis Surgery
I am a non-smoker and do not use nicotine products. I understand the potential risk of second-hand 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 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 surgery if I continue smoking.
It is important to refrain from smoking at least 6 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 time frame, and 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 which will prove the presence of Nicotine. If positive, your surgery may be cancelled and your surgery, scheduling fee, and other prepaid amounts may be forfeited. Honestly disclose smoking to your surgeon.
Sleep Apnea / CPAP: Individuals who have breathing disorders such as "Obstructive Sleep Apnea" and who may rely upon CPAP devices (continuous positive airway pressure) or utilize nighttime oxygen are advised that they are at a substantive risk for respiratory arrest and death when they take narcotic pain medications following surgery. This is an important consideration when evaluating the safety of surgical procedures in terms of very serious complications, including death, that relate to pre-existing medical conditions. Surgery may be considered only with monitoring afterwards in a hospital setting in order to reduce risk of potential respiratory complications and to safely manage pain following surgery.
Please consider the following symptoms of sleep apnea:
I am frequently tired upon waking and throughout the day
I have trouble staying asleep at night
I have been told that I snore or stop breathing during sleep
I wake up throughout the night or constantly turn from side to side
I have been told that my legs or arms jerk while I'm sleeping
I make abrupt snorting noises during sleep
I feel tired or fall asleep during the day
It is important for you to inform and discuss any of the above symptoms that you have experienced with your surgeon.
DVT/PE Risks and Advisory: There is a risk of blood clots, Deep Vein Thrombosis (DVT) and Pulmonary Embolus (PE) with every surgical procedure. It varies with the risk factors below. The higher the risk factors, the greater the risk and the more involved you must be in both understanding these risks and, when permitted by your physician, walking and moving your legs. There may also be leg stockings, squeezing active leg devices, and possibly medicines to help lower your risk.
There are many conditions that may increase or affect risks of clotting. Inform your doctor about any past
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or present history of any of the follo	wing:				
Past History of Blood Clots Family History of Blood Clots Birth Control Pills					
Hormone Stimulating Drug Swollen Legs	js				
History of Cancer					
Large Dose Vitamins					
Varicose Veins Past Illnesses of the Heart	. Liver. Luna	. or Gastro	intestinal	Tract.	
History of Multiple Spontar					
I understand the risks relat discussed with my surgeon					
Early ambulation wher	า allowed				
Compression devices	(SCD/ICD)				
Anticoagulation Proto	cols when All	lowed			
For high risk patients, the risks of \ If your surgery is elective and you'r elective surgery.					
available, email, and regular mail. aid in any necessary treatments. Planswering machine if any urgent messages. All attempts will be made. Please confirm below all acceptable.	lease do not or emergen de to preserv	leave a me t situation re your priv	essage at exists, a acy in ac	ter hours or o as there is a cordance with	n weekends on the office delay in retrieving such
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DISCLAIMER Informed-consent documents are treatment of a disease or condition including no surgery. The informe should generally meet the needs of	n along with d-consent pr	disclosure rocess atte	of risks mpts to	and alternative define principle	e forms of treatment(s)
However, informed-consent docum of care and risks encountered. information which is based on all knowledge.	Your plastic	surgeon	may pro	vide you wit	h additional or different
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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.



# CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1.	I hereby authorize Dr.	Jacob Gerzenshtein and su	uch assistants as ma	v be selected to	perform <b>Tenol</b>	vsis Surgery.

I have received the following information sheet: Tenolysis Surgery.

- 2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the 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 about 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 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. I realize that not having the operation is an option. I opt out of having this procedure \_\_\_\_\_.

- 12. 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	EATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12). HE EXPLANATION.	
Patient or Person Authori	zed to Sign for Patient	
Date/Time	Witness	