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INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you of tenolysis surgery, its risks, as well as alternative treatments.

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. 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.

RISKS OF TENOLYSIS SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with tenolysis surgery 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 the risks, potential complications, and consequences of tenolysis surgery.

<u>Bleeding-</u> It is possible, though unusual, to experience a bleeding episode during or after surgery. Intraoperative blood transfusions may be required. Should post-operative bleeding occur, it may require an emergency treatment to drain the accumulated blood or blood transfusion. Do not take any aspirin or anti-inflammatory medications for ten days before surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. If blood transfusions are needed to treat blood loss, there is a risk of blood related infections such as hepatitis and the HIV (AIDS). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

<u>Infection</u>- Infections after tenolysis surgery may occur, requiring additional treatment. There is the possibility of additional scarring from an infection. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary.

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.

<u>Inability to Restore Function</u>- 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.

<u>Change in Skin Sensation</u>- A diminished (or loss) of skin sensitivity in the finger, hand or forearm may occur and not totally resolve after tenolysis surgery.

<u>Rupture of Tendon</u> - 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>Skin Contour Irregularities</u>- Contour irregularities and depressions may occur after tenolysis surgery. Visible and palpable wrinkling of skin can occur. Residual skin irregularities at the ends of the incisions or "dog ears" are always a possibility and may require additional surgery. This may improve with time, or it can be surgically corrected.

Skin Discoloration / Swelling- Some bruising and swelling normally occurs following surgery. The skin in or near the surgical site can appear either lighter or darker than surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods of time and, in rare situations, may be permanent.

<u>Damage to Associated Structures</u>- Structures such as nerves, blood vessels, bone 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.

<u>Scarring</u>- All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur both 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. There is the possibility of visible marks in the skin from sutures. Scars may limit motion and function. There is the possibility that scarring can contribute to the recurrence of tenolysis. In some cases scars may require surgical revision or treatment.

<u>Fat Necrosis</u>- 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 of contour irregularities in the skin that may result from fat necrosis.

<u>Surgical Anesthesia</u>- Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

<u>Delayed Healing</u>- Wound disruption or delayed wound healing is possible. Depending on the type of surgery performed, complete healing may be prolonged. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. **Smokers have a greater risk of skin loss and wound healing complications.**

<u>Wound Breakdown</u>- 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.

<u>Additional Incisions Necessary</u>- 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.

<u>Abnormal Tendon Position-</u> 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.

<u>Allergic Reactions-</u> In rare cases, local allergies to tape, suture materials and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur to drugs used during surgery and prescription medications. Allergic reactions may require additional treatment.

<u>Pain-</u> You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after tenolysis surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue.

<u>Shock</u>- 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.

<u>Sutures</u>- 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.

<u>Seroma</u>- Fluid accumulations infrequently occur in between the skin and the underlying tissues. Should this problem occur, it may require additional procedures for drainage of fluid.

<u>Cardiac and Pulmonary Complications</u>Surgery, especially longer procedures, may be associated with the formation of, or increase in, blood clots in the venous system. Pulmonary complications may occur secondarily to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary and fat 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 blood clots or swollen legs 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.

ADDITIONAL ADVISORIES

<u>Unsatisfactory Result-</u> Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. There is the possibility of an unsatisfactory result from the tendon repair surgery. This would include risks such as skin and soft tissue loss, wound disruption, chronic pain, loss of hand function, visible deformities, poor healing, and loss of sensation. There is the possibility that hand function after tenolysis surgery may not be adequate for return to your regular occupation. It may be necessary to perform additional surgery to attempt to improve your results.

<u>Female Patient Information-</u> It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you believe you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

<u>Medications</u>- There are many adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. 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 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. 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.

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

Patients who are currently smoking, use tobacco products, or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying, delayed healing, and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smokers 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 this type of complication. Please indicate your current status regarding these items below:

nm a non-smoker and sing surgical complica	do not use nicotine productions.	ets. I understand the ri	isk of second-hand smok	е
nm a smoker or use to g or use of nicotine pr	obacco / nicotine products.	I understand the risk	of surgical complications	

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.

ADDITIONAL SURGERY NECESSARY

Other surgical procedures may be needed to overcome finger joint stiffness caused by tendon scarring. In some situations, a tendon graft may be necessary if tenolysis surgery is not successful. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with tenolysis surgery. Other complications and risks can occur but are even more uncommon. 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.

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 splints should <u>not</u> be removed unless instructed by your plastic surgeon or hand therapist. Successful restoration of tendon function depends on both surgery and subsequent hand rehabilitation. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care and hand rehabilitation, return for aftercare, and promote your recovery after surgery.

HEALTH INSURANCE

Depending on your particular health insurance plan, tenolysis surgery may be considered a covered benefit. Please review your health insurance subscriber-information pamphlet, call your insurance company, and discuss this further with your plastic surgeon. **Many insurance plans exclude coverage for secondary or revisionary surgery**.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, anesthesia, laboratory tests, and outpatient hospital charges, depending on where the surgery is performed. Additional charges may include hand rehabilitation therapy after surgery. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the injury or surgery. Secondary surgery or hospital day-surgery charges involved with revisionary surgery would also be your responsibility. Health insurance may not completely cover the costs of surgery and hand rehabilitation. You may require more hand rehabilitation services than your insurance plan covers. In signing the consent for this surgery/procedure, you acknowledge that your have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

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 no surgery. 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 of your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1.	I hereby authorize Dr the following procedure or treatment:	and such assistants as may be selected to perform
	TENOLYSIS SURGERY	
	I have received the following information sheet:	
	INFORMED CONSENT – TENOLYSIS SURGERY	
2.	I recognize that during the course of the operation conditions may necessitate different procedures the physician and assistants or designees to perform such her professional judgment necessary and desirable. include all conditions that require treatment and are no begun.	an those above. I therefore authorize the above h other procedures that are in the exercise of his or The authority granted under this paragraph shall
3.	I consent to the administration of such anesthetics conforms of anesthesia involve risk and the possibility of c	
4.	I acknowledge that no guarantee or representation has obtained.	s been given by anyone as to the results that may be
5.	I consent to be photographed or televised before, durperformed, including appropriate portions of my bor provided my identity is not revealed by the pictures.	
6.	For purposes of advancing medical education, I cons room.	sent to the admittance of observers to the operating
7.	I consent to the disposal of any tissue, medical devices	s or body parts which may be removed.
8.	I consent to the utilization of blood products should his/her appointees, and I am aware that there are pote	
9.	I authorize the release of my Social Security number medical-device registration, if applicable.	per to appropriate agencies for legal reporting and
10.	I understand that the surgeons' fees are separate from are agreeable to me. If a secondary procedure is necessary	
11.	I realize that not having the operation is an option.	
12.	IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I a. THE ABOVE TREATMENT OR PROCEDURE TO b. THERE MAY BE ALTERNATIVE PROCEDURES c. THERE ARE RISKS TO THE PROCEDURE OR T	BE UNDERTAKEN OR METHODS OF TREATMENT
	I CONSENT TO THE TREATMENT OR PROCEDURE SATISFIED WITH THE EXPLANATION.	AND THE ABOVE LISTED ITEMS (1-12). I AM
	Patient or Person Authorized to Sign for Patient	 ,

Date _

Witness