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INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about chemical injection of spider veins and skin treatment procedure(s), its risks, and alternative treatment.

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

Chemical injections with hypertonic saline (salt water) and other chemical have been performed for many years to treat spider veins. Conditions such as sun damage, wrinkling, and uneven pigmentation may be associated with spider veins but will not be improved by this local injection. The injections cause sclerosis or scarring of the blood vessel which can result in permanent or temporary improvement in the spider vein. Only spider viens that are small or the size of a small spider's leg can be treates with these non-invasive techniques. There are many different techniques and regimens for the treatment of spider viens including laser treatment, chemical-peeling, and skin treatment medications. In some situations, spider vien injections may be performed at the time of other surgical procedures.

Spider vien injection with solutions and other skin treatment procedures are not an alternative to surgical removal, laser treatment, or vein stripping for larger more pronounced blood vessels or lesions.

ALTERNATIVE TREATMENTS

Alternative forms of management include not treating the skin with chemical agents or other medications. Improvement of skin lesions may be accomplished by other treatments such as dermabrasion, laser treatment, or surgery to remove or treat the spider veins. Risks and potential complications are associated with alternative forms of treatment.

RISKS OF CHEMICAL INJECTION OF SPIDER VEINS-

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 a 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 chemical injection of spider veins or small vascular lesions.

<u>Infection</u>- Although infection following chemical injection is unusual, bacterial, fungal, and viral infections can occur. **Herpes simplex virus** infections around the mouth can occur /reoccur following a chemical injection. This applies to both individuals with a history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications must be prescribed and taken both prior to and following the procedure in order to suppress an infection from this virus. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional procedures may be necessary.

<u>Scarring</u>- Although good wound healing after a procedure is expected, abnormal scars may occur within the skin and deeper tissues. In rare cases, keloid scars may result. 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. In some cases scars may require surgical revision or treatment.

<u>Color Change</u>- Chemical agents can permanently lighten the natural color of your skin. There is the possibility of irregular color variations within the skin including areas that are both lighter and darker. Permanent darkening of skin has occurred after chemical peels. A line of demarcation between normal skin and skin treated with chemical peeling agent can occur. Redness after a chemical injection may persist for unacceptably long periods of time.

<u>Sunburn</u>- Certain types of chemical agents may leave the skin very prone to sun burn. Skin after a chemical injection may lack the normal ability to tan (darken) when exposed to sunlight.

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

<u>Lack of Permanent Results</u> – Chemical injection or other skin treatments may not completely improve or prevent recurrence of new or old spider veins or vascular lesions. No technique is 100% successful in the treatment of vascular lesions. Additional surgical or non-surgical procedures may be necessary to treat recurrent spider veins or vascular lesions. You may be required to continue with a skin care maintenance program or more treatments depending on your response to treatment.

<u>Delayed Healing</u>- 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. Skin healing may result in thin, easily injured skin. This is different from the normal redness in skin after a chemical injection. **Smokers have a greater risk of skin loss and wound healing complications.**

<u>Heart Problems</u>- Chemical injection preparations containg epinephrine or local anesthetics have been reported to produce abnormal heart beats that may require medical treatment should they occur during the procedure. This is usually a self-limiting problem.

Skin Discoloration / Swelling- Some swelling normally occurs following a chemical injection. The skin in or near the procedure site can appear either lighter or darker than surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods and, in rare situations, may be permanent. Bruising is a common problem that should be expected following the procedure.

<u>Skin Sensitivity-</u> Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur. Usually this resolves during healing, but in rare situations it may be chronic.

<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 and sedation.

<u>Pain-</u> You will experience pain during and after your treatment. Pain of varying intensity and duration may occur and persist after surgery. Very infrequently, chronic pain may occur after chemical injection procedures.

<u>Unknown Risks</u>- There is the possibility that additional risk factors of chemical injections and skin treatments may be discovered.

<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 a poor result from these procedures. This would include risks such as unacceptable visible deformities, skin slough, loss of function, poor healing, permanent color changes in the skin, loss of sensation, and recurrent or persistent spider veins or vascular lesion. It may be necessary to perform additional procedures to attempt to improve your results and additional treatments require additional fees depending on the situation.

ADDITIONAL ADVISORIES

<u>Long-Term Results</u>- Subsequent alterations in appearance may occur as the result of aging, weight loss or gain, sun exposure, pregnancy, menopause, or other circumstances not related to spider vein injection. Spider vien injection does not arrest the aging process or produce permanent removal of the vascular lesion in some cases. Future surgery or other treatments may be necessary to maintain you results.

Skin Lesion Recurrence- Skin lesions can recur after a chemical injection or skin treatments. Additional treatment or secondary surgery may be necessary.

<u>Skin Cancer / Skin Disorders</u>- Chemical injections and skin treatment procedures do not offer protection against developing skin cancer or skin disorders in the future.

<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.

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 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, 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 this type of complication. Please indicate your current status regarding these items below:

I am a non-smoker and do not use nicotine products. I understand the 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.

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.

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.

<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 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.

ADDITIONAL TREATMENT OR SURGERY NECESSARY

There are many variable conditions which influence the long term result of chemical injection of spider veins and other skin treatments. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with these procedures. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other 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, on the results that may be obtained.

PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for the success of your outcome. Postoperative instructions concerning appropriate restriction of activity, use of dressings, and use of sun protection must be followed in order to avoid potential complications, increased pain, and unsatisfactory result. Your physician may recommend that you utilize a long-term skin care program to enhance healing following a chemical injection. Successful post-operative function depends on both treatment and subsequent care.

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, return for aftercare, and promote your recovery after surgery.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical procedures such as chemical injections for spider veins or any complications that might occur from the procedure. Please carefully review your health insurance subscriber-information pamphlet or contact your insurance company for a detailed explanation of their policies. **Most insurance plans exclude coverage for secondary or revisionary surgery**.

FINANCIAL RESPONSIBILITIES

The cost of your procedure involves several charges for the services provided. The total includes fees charged by your surgeon, the cost of surgical supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the surgery is performed. 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 procedure. Secondary procedure or hospital day-surgery charges involved with revision will also be your responsibility. 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 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.

INFORMED CONSENT – CHEMICAL INJECTION OF SPIDER VEINS CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1.	I hereby authorize Dr and such assistants as may be selected to perform the following procedure or treatment:
	CHEMICAL INJECTION OF VASCULAR LESIONS OR SPIDER VIENS and TREATMENTS
	I have received the following information sheet:
	INFORMED CONSENT - CHEMICAL INJECTION OF SPIDER VEINS
2.	I recognize that during the course of the procedure 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 acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.
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 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.	realize that not having the procedure is an option.
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 (1-12). I AM SATISFIED WITH THE EXPLANATION.
	Patient or Person Authorized to Sign for Patient
	Date Witness