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Aesthetic, Breast and Reconstructive Surgery



INFORMED CONSENT – CHEMICAL SKIN-PEEL AND SKIN TREATMENTS

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you concerning chemical skin-peel and skin treatment procedures, the associated 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 treatment as proposed by your plastic surgeon and agreed upon by you.

GENERAL INFORMATION

Chemical skin-peel and other skin treatments have been performed for many years to treat a variety of skin disorders. Conditions such as sun damage, wrinkling, and uneven pigmentation may be treated with these non-invasive techniques. There are many different techniques and regimens for the application of chemical-peel and skin treatment medications. In some situations, chemical peels may be performed at the time of other surgical procedures.

Chemical-skin peel procedures are not an alternative to skin tightening surgery when indicated.

ALTERNATIVE TREATMENT

Chemical skin-peel and other skin treatments are elective procedures. Alternative treatment would consist of not undergoing such treatments. Improvement of skin lesions and skin wrinkles may be accomplished by other treatments such as dermabrasion, laser treatment, or surgery to tighten loose skin. Risks and potential complications are associated with alternative surgical forms of treatment.

RISKS OF CHEMICAL SKIN-PEEL AND SKIN TREATMENTS

Every treatment 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 skin-peel and other forms of skin treatment.

Bleeding: It is possible, though unusual, to experience a bleeding episode during or after treatment. Should post-treatment bleeding occur, it may require emergency treatment to drain accumulated blood or blood transfusion. Intra-operative blood transfusion may also be required. Aspirin, anti-inflammatory medications, non-prescription "herbs", and dietary supplements can increase the risk of bleeding. If blood transfusions are needed to treat blood loss, there is a risk of blood related infections such as hepatitis and the Human Immunodeficiency Virus (the virus that causes AIDS).

Infection: Infection is unusual after treatment. If you have a history of **Herpes simplex virus** infections around the mouth, it is possible that an infection can recur following chemical peel and collagen shot treatments. Specific medications must be prescribed prior to the skin treatment procedure in order to suppress an infection from this virus. Should an infection occur, additional treatment including antibiotics, hospitalization, or surgery may be necessary.

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Patient Initials

01/07/08 version

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Change in skin sensation: It is possible to experience diminished (or loss) of skin sensation in areas that have had treatment. Diminished (or complete loss of skin sensation) may not totally resolve.

Skin Sensitivity: Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after treatment. Usually this resolve during healing, but in rare situations it may be chronic.

Scarring: Although good wound healing after a skin treatment is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color than surrounding skin. Scar appearance may also vary within the same scar, exhibit contour variations and "bunching" due to the amount of excess skin. Scars may be asymmetrical (appear different between right and left side of the body). Additional treatments including surgery may be necessary to treat abnormal scarring. Scarring has not been found to occur with modified phenol formula.

Color change- Chemical peel 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, particularly in darker skin-toned patients. A line of demarcation between normal skin and skin treated with chemical peel treatment can occur. Redness after a chemical peel may persist for unacceptably long periods of time.

Skin lesion recurrence- Skin lesions in some situations can recur after a chemical skin-peel or skin treatments. Additional treatment or secondary surgery may be necessary.

Skin cancer/skin disorders- Chemical skin-peels and skin procedures may not offer protection against developing skin cancer or skin disorders in the future.

Delayed healing- It may take longer than anticipated for healing to occur after a chemical skin-peel or other treatments. Skin healing may result in thin, easily injured skin. This is different from the normal redness in skin after a chemical peel. **Smokers have a greater risk of skin healing complications.**

Allergic Reactions: In rare cases, local allergies to tape, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur to drugs used during treatment and prescription medications. Allergic reactions may require additional treatment.

Specific side effects associated with skin treatment agents:

Collagen: redness, swelling, bruising

Isolagen: patients age >60 not candidates for use

Dermalogen: hyperpigmentation, erythema

Artecoll: swelling, bruising, sensitivity, not FDA-approved

Hyaluronic Acid Derivatives: erythema, ecchymosis, acneiform dermatitis, intermittent swelling of implant

Gore-Tex: unnatural feel, migration and extrusion, misalignment of material

Soft-Form: extrusion or exposure of material, migration

Radiance: migration of deposits

Long Term Results: Subsequent alterations in the appearance of your body may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause or other circumstances not related to your skin treatment. Chemical peel or other skin treatments may not completely improve and will not prevent future skin wrinkling. None of these techniques can reverse the signs of skin aging. Additional surgical procedures may be necessary to further tighten loose skin. You may be required to continue with a skin care maintenance program after a chemical peel procedure.

Heart problems- Chemical peel preparations have been reported to produce abnormal heart beats that may require medical treatment should they occur during the procedure. This is a potentially serious problem.

Unknown risks- There is the possibility that additional risk factors of chemical skin-peel and skin treatments may be discovered.

Anesthesia- Both local and general anesthesia involves risk. There is the possibility of complications,

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injury, and even death from all forms of anesthesia or sedation.

Unsatisfactory result- Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. You may be disappointed with the results of chemical skin-peel or other skin treatments. This would include risks such as asymmetry, unsatisfactory or highly visible scar location, unacceptable visible deformities, poor healing, and loss of sensation. It may not be possible to correct or improve the effects of scars. Additional surgery may be required to improve results.

ADDITIONAL ADVISORIES:

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, 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:

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

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

Female Patient Information: 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.

Mental Health Disorders and Elective Treatment- It is important that all patients seeking to undergo elective treatment have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional treatment and often are stressful. Please openly discuss with your surgeon, prior to procedure, 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 treatment, effects on mental health cannot be accurately predicted.

Medications: 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 treatment, 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.

ADDITIONAL TREATMENT NECESSARY

Should complications occur, additional treatments may be necessary. Secondary treatment may be necessary to obtain optimal results. Even though risks and complications occur infrequently, the risks cited are particularly associated with chemical skin-peel and skin treatments. Other complications and risks can occur but are even more uncommon. The practice of medicine 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. With chemical peel and other skin treatments, it may not be possible to achieve optimal results with a single procedure. This may require multiple treatment sessions to produce a final outcome.

PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important

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that the treated skin areas are not 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 not be removed unless instructed by your plastic surgeon. Successful post-treatment function depends on both treatment and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation around implants and the need for return to treatment. It is wise to refrain from intimate physical activities after treatment 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 treatment.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic treatment procedures or any complications that might occur from treatment. Please carefully review your health insurance subscriber-information or contact your insurance company for a detailed explanation of their policies. **Most insurance plans exclude coverage for secondary or revisionary treatment.**

FINANCIAL RESPONSIBILITIES

The cost of treatment involves several charges for the services provided. The total includes fees charged by your surgeon, the cost of supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the treatment is performed. Depending on whether the cost of treatment 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 treatment. Secondary treatment or other charges involved with revision treatment will also be your responsibility. **In signing the consent for this procedure, you acknowledge that you 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 treatment. 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 state of medical knowledge.

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

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

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CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr. _____ and such assistants as may be selected to perform the following procedure or treatment: **Chemical Skin-Peel and Skin Treatments**

I have received the following information sheet:

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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 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 consent to the disposal of any tissue, medical devices or body parts which may be removed.
8. I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
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.
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 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 _____