ENCHANTED

MEDICAL AESTHETICS

Standard Operating Procedures Manual

Clinical Policies & Procedures

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FACT SHEET **244**

OVERVIEW OF TREATMENTS

CLINICAL POLICIES AND PROCEDURES
TERMS AND DEFINITIONS

OVERVIEW

In today's fast paced and stressful environment, it is a challenge to keep skin looking healthy and youthful. Advancements in [medical] technology, allow us to go beyond traditional "medical or salon techniques" to provide treatment.

Botulinum toxin injections, dermal fillers injections, mesotherapy (Lipo-Dissolve), platelet rich plasma (PRP) injections, cosmetic sclerotherapy, skin rejuvenation, cosmetic laser, medical grade chemical peels, and microdermabrasion set [Physician Practice Name/ Medspas] apart from "others" in the field. Our staff will design a personalized program to keep your skin looking young and healthful for years to come.

Botulinum Toxin – Type A is a highly effective treatment for frown lines, worry lines, forehead wrinkles and crow's feet. It will give your skin a soft, smooth, natural appearance. The sensation associated with this procedure is minimal and most patients compare it to a bug bite. This procedure can be done rather quickly [i.e. during a lunch break] and a patient may return back to work with no down time.
Dermal Fillers (Soft Tissue Fillers) are medical device implants approved by the Food and Drug Administration (FDA) for use in helping to create a smoother and/or fuller appearance in the face, including nasolabial folds, cheeks and lips and for increasing the volume of the back of the hand. Soft tissue fillers have a temporary effect, because they contain materials that are absorbed by the body over time. The FDA has approved only one product made from a material that remains in the body and is not absorbed. Some soft tissue fillers also contain lidocaine, which is intended to decrease pain or discomfort related to the injection.

The materials used in soft tissue fillers include:

- **Collagen:** Collagen is a type of protein that is a major part of skin and other tissues in the body. Sources of purified collagen used in soft tissue fillers can be from cow (bovine) or human cells. The effects of collagen fillers generally last for 3-4 months. They are the shortest lasting of injectable filler materials.
- **Hyaluronic acid:** Hyaluronic acid is a type of sugar (polysaccharide) that is present in body tissues, such as in skin and cartilage. It is able to combine with water and swell when in gel form, causing a smoothing/filling effect. Sources of hyaluronic acid used in dermal fillers can be from bacteria or rooster combs (avian). In some cases, hyaluronic acid used in dermal fillers is chemically modified (crosslinked) to make it last longer in the body. The effects of this material last approximately 6 – 12 months.

- **Calcium hydroxylapatite:** Calcium hydroxylapatite is a type of mineral that is commonly found in human teeth and bones. For wrinkle filling in the face or for the hand, calcium hydroxylapatite particles are suspended in a gel-like solution and then injected into the wrinkle in the face or under the skin in the back of the hand. The effects of this material last approximately 18 months.
- **Poly-L-lactic acid (PLLA):** PLLA is a biodegradable, biocompatible man-made polymer. This material has wide uses in absorbable stitches and bone screws. PLLA is a long lasting filler material that is given in a series of injections over a period of several months. The effects of PLLA generally become increasingly apparent over time (over a period of several weeks) and its effects may last up to 2 years.

Skin Rejuvenation/Photo-Facial is a series of treatments intended to improve the appearance of sun-damaged or aged skin. It can also reduce redness and flushing, such as seen in a skin condition known as Rosacea. Early clinical experience has shown dramatic improvements [on average, 90%] in skin color and texture of the face, neck, chest and back. Mild acne scars can be diminished, and large pores and fine lines can be reduced. Most significantly, patients report no “downtime” in their daily activities.

Laser Hair Removal - Imagine waking up in the morning with smooth [hair-free] skin and not having to shave, pluck, wax or bleach unwanted hair. Laser hair removal is done with a specific beam of light that has the ability to permanently disable and reduce unwanted body hair. Depending on the amount of hair and the size of the area being treated, sessions may vary from a few minutes to an hour.

Microdermabrasion is often called a power peel. It is a holistic option that rejuvenates skin using tiny diamond shaped crystals to slough off dead skin cells, promoting natural collagen. The treatments are fast and pain-free, leaving little or no redness or downtime. This unique approach improves skin texture regardless of skin type. Power peels are a safe, non-surgical approach to skin care. The power peel has often been referred to as the “lunch time peel” because it takes only about 15-30 minutes per treatment and will not interrupt a busy schedule. Microdermabrasion is also used in conjunction with medical grade chemical peels to enhance the effects of the peel and is referred to as a Micro-Peel to patients.

Mesotherapy is the use of injections directly into the Mesoderm to treat small fat pocket accumulation locally. **Mesotherapy** uses PC/DC-50/42 (Phosphatidylcholine (PC) / Deoxycholate (DC)) and the new FDA approved drug “Kybella” (Deoxycholate acid (10mg/1ML)) for the lysis of adipose fat that is compartmentalized. Other terms for small fat pocket reduction includes “Lipo-Therapy” and “Lipo-Dissolve”. When micro injections of the mesotherapy solution is administered into the targeted area, the solution is quickly absorbed into the fat cells and causes a breakdown of those cells. The dissolution products of the fat cells are removed in a natural manner, similar to the way blood is removed within a bruise through relocation and resorbed thus creating reduction of unwanted small fat deposits in specific body areas.

Micro-needling (Scar Revision) uses either micro-needling devices (aka pens) or the use of needle rollers to mechanically break fibrils or elastin collagen that has contracted and has formed depression scars or static rhytids. Micro-needling is indicated for patient conditions such as acne scars, cellulite (Grade III), static rhytids, and overall facial and body part skin rejuvenation. Dependent upon the condition being presented there are numerous options concerning topical solutions, needle depth, devices, and protocols. Typical results per treatment is between 40-50% correction of the original indication. Multiple treatments are necessary for the elimination of the various uses and are not guaranteed.

Platelet Rich Plasma (PRP) is blood plasma that contains a concentrated source of autologous platelets. The platelets collected in PRP are activated by adding thrombin and calcium chloride which induces the release of these factors by degranulation of the alpha granules produced. Several forms of PRP or PRP-derived products exist for different conditions. PRP can be liquid or gel formed but a fibrin matrix is often used for meniscus repair, rotator cuff injury, and ACL reconstruction. PRP contains stem cells that are concentrated which allows for cell division for growth as well as being able to attract additional stem cells to the repair site. Regeneration occurs within the tissues and fibrils ensues while initiating growth and repair for up to (1) month after these injections. The result is new, healthy tissues that is permanent and is used aesthetically or medically dependent upon patient presentation.

Sclerotherapy (Injection) is a cosmetic procedure for the elimination of asymptomatic and unwanted veins for patients. Cosmetic sclerotherapy involves the use of injections of small amounts of solutions (sclerosant) to irritate the vein walls and achieve the ultimate closure of the vein. The functions of a sclerosant is to create endothelial injury within the vein resulting in thrombosis, thrombolysis, and fibrosis eliminating the unwanted veins permanently. The FDA has only approved (2) medications for the elimination of these veins; Sodium Tetradecyl Sulfate (STS) - Sodium 1-isobutyl-4ethyloctyl sulfate which is a synthetic long chain-fatty acid and Asclera™ (POL) - Hydroxy-polyethoxy-dodecane which is a synthetic long-chain fatty alcohol. Typically the treatment protocol is over a series of (3) treatments with an estimated 80% improvement between treatments. Maintenance treatments are needed for the majority of cosmetic sclerotherapy patients and short-term efficacy and correction should also be considered relating to future treatments.

Skin Tightening Procedures include the use of lasers or radio frequency devices to safely heat deep dermal tissues causing collagen reduction in the reticular (lower) dermis and coagulation of tissue in the papillary (upper) dermis. Controlled wounding of the papillary dermis allows for new collagen formation and remodeling while reduction of collagen to the reticular dermis allows for contraction of tissue. This is a non-ablative type of procedure and typically include Class II light energy devices and requires multiple treatments for the desired effect. Typically, these devices are safe for all skin types and has multiple Non-FDA

uses such as the shrinkage of sebaceous glands associated with moderate and severe acnes. It requires a number of treatments and is dependent upon patient tissue response, body location, and the light energies introduced to the skin. Remodeling of collagen within tissue occurs in as little as (3) weeks and can last as long as (9) to (12) months depending upon the individual. Areas that can be treated successfully include thighs, abdomen, knees, face, and neck areas.

The Clinical policies and procedures contained herein have been developed using the latest standards of care using multiple sources from federal and state agencies, State Boards of Medicine, and outside Professional Medical Societies.

BOTULINUM TOXIN TREATMENTS

CLINICAL POLICIES AND PROCEDURES

SECTION 1

PURPOSE

To ensure safe and effective treatment of clients undergoing Botulinum Toxin – Type A administration at the **Enchanted Medical Aesthetics**, the following policies and procedures have been developed.

POLICY

A Registered Nurse [RN], Physician Assistant or licensed medical personnel with current state licensure shall be able to assess, consult and treat clients with Botox® following the guidelines set herein. In the state of California, the medical director or a physician assistant must perform a good faith examination prior to the use of Botox®.

SETTING

The Nurse Practitioner, Physician Assistant can perform the administration of Botox® in various settings and locations, such as but not limited to:

- Physician Office
- Satellite clinic / health care office(s)
- MedSpa Setting authorized by the Medical Director

All Botulinum Toxin Type A (i.e. Botox®, Xeomin®, Dysport®) administration procedures shall be performed in a clean, safe environment, equipped with proper sharps disposal system, and universal precautions in place.

SUPERVISION

The Nurse Practitioner, Physician Assistant or licensed medical personnel shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary.

All adverse reactions such as ptosis, diplopia, lower eyelid retraction, and weakening of the lacrimal pump shall be reported immediately to the Medical Director. Adverse reaction(s) shall be documented in the client's chart.

PATIENT CONDITIONS

The Nurse Practitioner, Physician Assistant or licensed medical personnel will not knowingly treat any clients with allergies to eggs, egg products, albumin, any clients with significant autoimmune or neurological diseases, or pregnant clients. The Nurse Practitioner, Physician Assistant or licensed medical personnel will only treat the areas of the face upper and lower that they have been trained on.

BOTULINUM TOXIN, TYPE A PROCEDURE

The Nurse Practitioner, Physician Assistant or licensed medical personnel will:

1. Complete assessment and a medical history questionnaire with all new clients.

2. Clients with a history of allergies to human albumin, clients with significant neurological and autoimmune diseases, or pregnant clients will be denied treatment.

3. Upon passing medical screening, client will be fully informed of risks, benefits, and potential adverse reactions and an informed consent will be signed.

4. Botulinum Toxin, Type A (i.e. Botox®, Xeomin®, Dysport®) shall be stored in a freezer [-5 degree C or lower] or refrigerator [2-8 degree C] until ready for use. Once reconstituted, it must be refrigerated [2-8 degree C], not refrozen. Reconstituted Botox should be clear, colorless and free of particulate matter.

5. Botulinum Toxin, Type A (i.e. Botox®, Xeomin®, Dysport®) shall only be reconstituted just prior to use and should be used within the first 4 hours according to the manufacturer. However, medical papers suggest it can be refrigerated up to 30 days without any loss of efficacy. Gently rotate the vial and record the date and time of reconstitution on the label.

6. Vacuum will be released, using a 21/22-gauge, 2.5 inch length-needle prior to reconstitution. If no vacuum is present the Botox vial will be sent back to the manufacturer and a new vial shall be used following the same procedure.

7. Botulinum Toxin, Type A (i.e. Botox®, Xeomin®, Dysport®) should be reconstituted using 2.5 ml of non-preserved saline[1] [0.9%] as a diluent, resulting in a 4.0 units per 0.1cc. A 3-5cc syringe containing non-preserved saline is attached to the 21/22 gauge needle [at a 45° angle] and SLOWLY injected into the vial. Allow the saline to

[1] Allergan & Merz Pharma recommends using 2.5ml of non-preserved saline resulting in 4.0 units per 0.1cc. Galderma (Dysport) recommends 3.0ml of non-preserved saline resulting in 10.0 units per 0.1cc.

flow down the sides of the vial, thus minimizing air bubble formation and not damaging the delicate neurotoxin and protein associated with the Botulism Toxin.

8. Botulinum Toxin, Type A (i.e. Botox®, Xeomin®, Dysport®) is gently drawn up into a 1ml tuberculin syringe using a 21/22 gauge needle. The injection is to be administered with a 30 or 31-gauge [½ inch needle].

9. Clients are injected while in a reclined or seated position.

10. Clients are asked to demonstrate dynamically the function of the muscle groups to be injected.

11. Prior to administration the Nurse Practitioner, Physician Assistant or licensed medical personnel will map out points of injection according to landmarks and location of muscle belly. The areas of administration will be the corrugator, procerus, frontalis, and orbicularis oculi muscles, mentalis, DAO, platysmal bands. [Corrugator and procerus muscles for frown lines, frontalis muscle for horizontal forehead lines, and orbicularis oculi muscle for crow's feet, lip flip, orange peel chin, neck bands, gummy smile]

    Note: increased toxin dose may be necessary in older and male clients.

12. In an effort to reduce the complications of ptosis the following steps should be adhered too:
    a. Administer at least 1cm above the central eyebrow and 1.5cm-2cm from the lateral canthus.
    b. Ensure the injected volume/dose is accurate and kept to a minimum.
    c. Avoid injection near the levator superioris, particularly in patients with larger brows.
    d. Medial corrugator injections should be placed 1cm above the bony supraorbital ridge.

If mild ptosis should occur the nurse will instruct the client that this will resolve within a few weeks and in the use of [over the counter] Vasocon to assist in alleviating the ptosis which will alleviate the immediate condition temporarily. The prescription drug Iopodine™ may also be prescribed by the attending physician or Medical Director if determined after examination of the patient. Ptosis or any other complications[2] shall be immediately reported to the Medical Director and documented in the client record.

[2] The medical provider shall be familiar with all general adverse reactions that can be associated with the administration of Botulinum Toxin Type A products. Refer to the manufacturer's publication within the product insert, "Adverse Reactions-General" enclosed with each vial of product.

13. Syringe is inserted perpendicular to the skin and completed at a depth just beneath the dermis, 0.1cc of Botox is injected into each site.

14. After each injection a cold compress consisting of a clean 4x4 gauze dipped in ice water is applied and gently massaged for a few seconds over the injection site.

15. When procedure is completed, the client will be educated to perform the dynamic facial expressions for the next hour, not to rub or manipulate the injection sites, not to lie down for a period of 4 hours, and to report any problems or complications to the office immediately.

16. Typically, the initial doses of reconstituted Botulinum Toxin – A induce chemical denervation of the injected muscles one to two days after procedure, increasing in intensity during the first week.

SAMPLE PRIOR HYPERHIDROSIS TREATMENT AUTHORIZATION LETTER

[Print on Physician's Office/Hospital Letterhead]

[Date_____]

[**Health plan/payer name]**
[Health plan/payer address]

Re: [**Insert patient's name]**
[Insert Group/policy/member identification number]

Dear Sir/Madam:

I am writing to seek prior authorization for the treatment of my patient, [**insert patient name**], who has severe primary axillary hyperhidrosis not adequately managed with topical agents and who requires treatment with botulinum toxin type A. This letter and the enclosed documents provide support for prior authorization for this treatment.

Severe primary axillary hyperhidrosis is a debilitating disorder characterized by markedly excessive sweating of the axillae which seriously limits patients' abilities to carry on daily activities. Severe primary axillary hyperhidrosis is diagnosed when there is focal, visible and excessive sweating of the axillae of at least 6 months duration without apparent cause that has at least 2 of the following characteristics: (1) sweating is bilateral and relatively symmetric, (2) impairs daily activities, (3) episodes occur at least once per week, (4) the age of onset was less than 25 years, (5) there is a positive family history, and (6) focal sweating stops during sleep. (Hornberger J, Grimes K, Naumann M, Glaser DA, et al. Recognition, diagnosis and treatment of primary focal hyperhidrosis. J Am Acad Dermatol. 2004;[full citation pending]; [copy enclosed].)

Severe primary axillary hyperhidrosis may be treated with a number of therapies depending upon the focal areas affected, the severity of the condition and response to less invasive therapies. Initial treatment usually comprises topical agents, such as prescription-strength aluminum chloride hexahydrate products. Botulinum toxin type A administration may be considered for patients who do not have an adequate response to treatment with topical agents. More invasive options include surgical resection of sweat glands and endoscopic transthoracic sympathectomy. (Idem.)

[**Insert brief summary of the patient's history including those findings that support the diagnosis of severe primary axillary hyperhidrosis and prior treatment history.]** Given the diagnosis of severe primary axillary hyperhidrosis with serious impairment of usual activities in this patient and the lack of adequate response to alternative therapies, I concluded that treatment with botulinum toxin type A is warranted in this case. **[If the patient presents for**

repeat treatment and the following is true, you may add: Botulinum toxin type A treatment has been effective and well-tolerated by the patient in the past. As botulinum toxin type - A treatment is reversible, the patient now presents for follow-up treatment, as expected.

Botulinum toxin type A was approved by the U.S. Food and Drug Administration on _____, 20___ for "[**insert final indication**]." (A copy of package insert reflecting updated labeling is enclosed.) Botulinum toxin type A has been shown to be a safe and effective treatment of severe primary axillary hyperhidrosis not managed adequately with topical agents in published clinical studies. (See enclosed: Naumann M, Lowe NJ. Botulinum toxin type A in treatment of bilateral primary axillary hyperhidrosis: randomised, parallel group, double blind, placebo controlled trial. Brit Med J. 2001;323:596-599. Naumann M, Hamm H, Lowe NJ. Effect of botulinum toxin type A on quality of life measures in patients with excessive axillary sweating: a randomized controlled trial. Brit J Dermatol. 2002;147:1218-1226.)

[If this payer does not have a policy/instruction on billing for hyperhidrosis procedures, you may add: Please provide instructions as to how you would like this procedure coded.**]** **[If the payer does have a policy/instructions on billing for hyperhidrosis procedures, you may add**: Per instructions we received from [**insert specific contact name**], this procedure was billed under code 646xx "**[insert full descriptor for code used**]."**]**

In summary, my patient, [**insert patient name**], suffers from severe primary axillary hyperhidrosis, which seriously impairs [his/her] ability to carry out the kinds of activities we all take for granted in our daily lives. Topical treatments have not provided adequate relief and treatment with botulinum toxin type A is warranted in this case. **[If the prior authorization is for repeat treatment and the following is true, you may add**: The patient has responded well to this treatment in the past.**]** If you have any questions about this patient or would like additional information to assist your review of this prior authorization request, please contact me at [**insert contact information**]. Thank you for your consideration.

Sincerely yours,

[**Insert physician's name and title**]

Enclosures: BOTOX® (botulinum toxin type A) package insert, NDC # 0023-1145-01

RECORD KEEPING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall be responsible for maintaining client records, including but not limited to client assessment, signed informed consent of risks, benefits, and potential adverse effects, number of treatments, treatment sites, number of injections, solution/concentration used, and the client response to treatment.

REQUIREMENTS FOR CLINICAL PERSONNEL

TRAINING / EDUCATION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall receive specialized training [and be certified] in the administration of Botox®. A Medical Doctor, Doctor of Osteopath, Advanced Practice Nurse experienced in this procedure, or a teaching institution specializing in this procedure, may perform this training and certification. Competencies to successfully demonstrate shall include:

- Mechanism of Action of the Botulinum Toxin, Type A Products
- Basic Theory of Treatment for Cosmetic Purposes
- Facial Anatomy
- Storage, preparation, and dilution of Botulinum Toxin A
- Safety, efficacy, and complication issues
- Assessment and identification of areas to be treated
- Safe application of injection techniques [minimum 8-hours hands on training]

COMPETENCIES & DOCUMENTATION

The Medical Director and/or [applicable licensure], shall

- Document [on the appropriate form] the initial evaluation and final determination recording satisfactory completion of training and competence.

- Evaluate of the competence of the Nurse Practitioner, Physician Assistant or licensed medical personnel on an annual basis and/or as needed if indicated by client dissatisfaction or efficacy issues.

- The evaluation shall be maintained in the personnel file of the Registered Nurse, Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].

DEVELOPMENT & APPROVAL OF STANDARDIZED PROCEDURE

The Clinical Policies and Procedures for the Administration of Botulinum Toxin, Type A products have been developed jointly by the Medical Director, Administrator, Advanced Practice Nurse and/or Registered Nurse. This procedure shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

_____ _____
Authorized Healthcare Personnel Date

_____ _____
Medical Director Date

_____ _____
Administrator Date

PERSONNEL AUTHORIZED TO PERFORM PROCEDURE

NAME	DATE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____

BRIEF MEDICAL HISTORY AND INFORMED CONSENT

Name_____Phone_____Age_____Ht_____Wt_____
Address_____City/State_____
Zip_____

MEDICATIONS:_____
___

ALLERGIES:_____

Women: Are you Pregnant?_____
Physician's
Name_____
Circle any of the following illnesses you have or have ever had in the past:
Myesthenia Gravis Hepatitis Eye Disease Autoimmune Disease
Vision Problems Numbness Muscle Weakness Amyotrophic Lateral Sclerosis (ALS)

Explain:
_____

Previous Hospitalizations/Operations:

_____
I understand the information on this form is essential to determine my medical and cosmetic needs and the provision of treatment. I understand that if any changes occur in my health I will report it to the office as soon as possible. I have read and understand the above medical questionnaire. I acknowledge that all answers have been recorded truthfully and will not hold any staff member responsible for any errors or omissions that I have made in the completion of this form.
Patient
Signature_____Date_____

CONSENT TO BOTULINUM TOXIN "A" TREATMENT
Botox® a neurotoxin produced by the bacterium Clostridium A. Botox® can relax the muscles on areas of the face and neck that cause wrinkles associated with facial expressions. Treatment with Botox can cause your facial expression lines or wrinkles to essentially disappear. Areas most frequently treated are: a) glabellar area of frown lines, located between the eyes; b) crow's feet (lateral areas of the eyes); and c) forehead wrinkles. Botox

is diluted to a very controlled solution and when injected into the muscles with a very thin needle, it is almost painless. Clients may feel a slight burning sensation while the solution is being injected. The procedure takes about 15-20 minutes and the results last 3-6 months. With repeated treatments, the results may tend to last longer.

RISKS AND COMPLICATIONS

It has been explained to me that there are certain inherent and potential risks and side effects in any invasive procedure and in this specific instance such risks include but are not limited to : 1) Post treatment discomfort, swelling, redness, and bruising, 2) Post treatment bacterial, viral, and/or fungal infection requiring further treatment, 3) Allergic reaction, 4) Minor temporary drop of eyelid(s) in approximately <1% of injections, this usually lasts 2-3 weeks, 5) Occasional numbness of the forehead lasting up to 2-3 weeks, 6) Transient headache, and 7) Flu-like symptoms may occur.

PREGNANCY, ALLERGIES & NEUROLOGIC DISEASE

I am not aware that I am pregnant, have any significant Neurologic disease, or have any allergies to the toxin ingredients, or to human albumin.

RESULTS

I am aware that when small amounts of purified botulinum ("BOTOX®") are injected into a muscle it causes weakness or paralysis of that muscle. This appears in 3-4 days and usually lasts 3-6 months but can be shorter or longer. In a very small number of individuals, the injection does not work as satisfactorily or for as long as usual. I understand that I will not be able to "frown" while the injection is effective but that this will reverse after a period of months at which time re-treatment is appropriate. I understand that I must stay in the erect posture and that I must not manipulate the area of the injection for the four hours post-injection period.

I hereby voluntarily consent to treatment with Botulinum Toxin Type A injection for the condition known as: Facial Dynamic Wrinkles. The procedure has been explained to me. I have read the above and understand it. My questions have been answered satisfactorily. I accept the risks and complications of the procedure.

_____ _____

Patient Signature Date Witness Signature Date

BOTULINUM TOXIN, TYPE A POST TREATMENT INSTRUCTIONS

- Avoid lying down for several hours following treatment.
- Facial exercise in the area of treatment is recommended [frown/smile 1 hour].
- Avoid manipulation of the area the first four-hours after procedure.

Note: These measures should minimize the possibility of ptosis.

- Treatment effects may take 3-8 days to appear.
- **The benefits may last 3-6 months, the average is 4 months.**
- A touch-up may be necessary in 1-2 weeks.
- Contact the practitioner as soon as possible after the eight [8th] day if you have not received the desired effect.

PRE-PROCEDURE QUESTIONNAIRE FOR BOTOX INJECTIONS

Patient Name: _____ Date: _____

History

Do you have:

Hypersensitivity to Botulinum A toxin products	□ Yes	□ No
Infection at the proposed injection site(s)	□ Yes	□ No
Bleeding Disorders	□ Yes	□ No
Cardiac Disease	□ Yes	□ No
Active Skin Disease	□ Yes	□ No

Do you or a family member have:

Amyotrophic Lateral Sclerosis	□ Yes	□ No
Motor Neuropathy	□ Yes	□ No
Myasthenia Gravis	□ Yes	□ No
Lambert-Eaton Syndrome	□ Yes	□ No
Facial Nerve Palsy	□ Yes	□ No

Are you:

Pregnant	□ Yes	□ No
Breast-feeding	□ Yes	□ No

Medications

Do you take or have recently been on any of the following medications:

Warfarin or Anti-Platelet Agents	□ Yes	□ No	Quinidin	□ Yes	□ No
Aminoglycosides	□ Yes	□ No	Magnesium Sulfate	□ Yes	□ No
Curare-like Nondepolarizing Blockers	□ Yes	□ No	Anticholinesterases	□ Yes	□ No
Lincosamides	□ Yes	□ No	Succinylcholine Chloride	□ Yes	□ No
Polymyxins	□ Yes	□ No			

Physical

Glabellar lines smoothed out by physically spreading them apart	□ Yes	□ No
Skin infection at site of injection	□ Yes	□ No
Evidence of muscular atrophy	□ Yes	□ No
Evidence of petechia or bruising	□ Yes	□ No
Facial Asymmetry	□ Yes	□ No
Ptosis	□ Yes	□ No
Deep dermal scarring	□ Yes	□ No
Thick sebaceous skin	□ Yes	□ No
Dermatochalasis (excessive redundant skin)	□ Yes	□ No

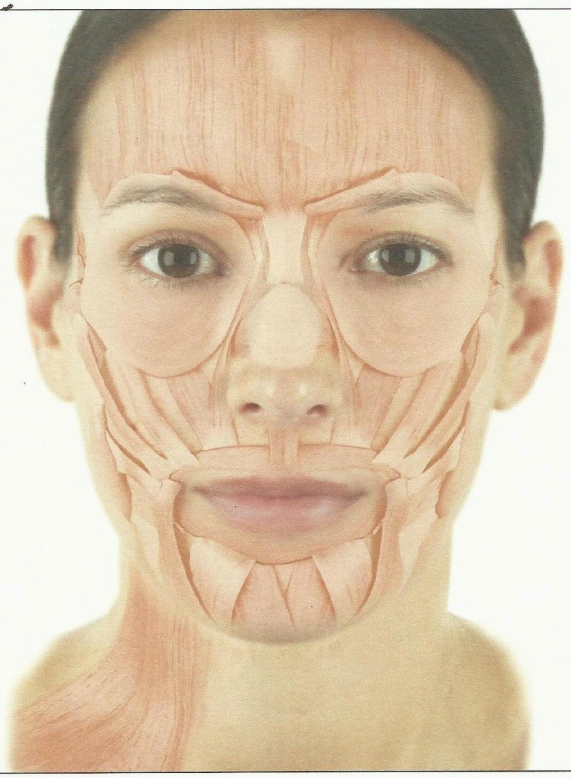
Physician/P.A. Signature: _____ Date: _____

MERZ AESTHETICS™

TREATMENT RECORD

Patient Name / ID: Date of Injection:

Anesthesia: Product:



Lot Number: Expiration Date:

_____ (mL) diluent Product size / total amount used:

Total per Treatment Area:

Notes/ Lot Stickers:

Practitioner Signature:

Dysport® Treatment Form

Patient Name (Please Print)

Chief Complaint

Date of Service (Treatment)

Dilution Used: 300 unit Vial

	Saline	# Units/1.0ml	# Units/0.1ml
○	2.0 cc	150 U/1.0ml	15 U/0.1ml
○	2.5 cc	120 U/1.0ml	12 U/0.1ml
○	3.0 cc	100 U/1.0ml	10 U/0.1ml
○	4.0 cc	75 U/1.0ml	7.5 U/.01ml

Dilution Used: 500 unit Vial

	Saline	# Units/1.0ml	# Units/0.1ml
○	2.5 cc	200 U/1.0ml	20 U/0.1ml
○	4.0 cc	125 U/1.0ml	12.5 U/0.1ml
○	5.0 cc	100 U/1.0ml	10 U/0.1ml

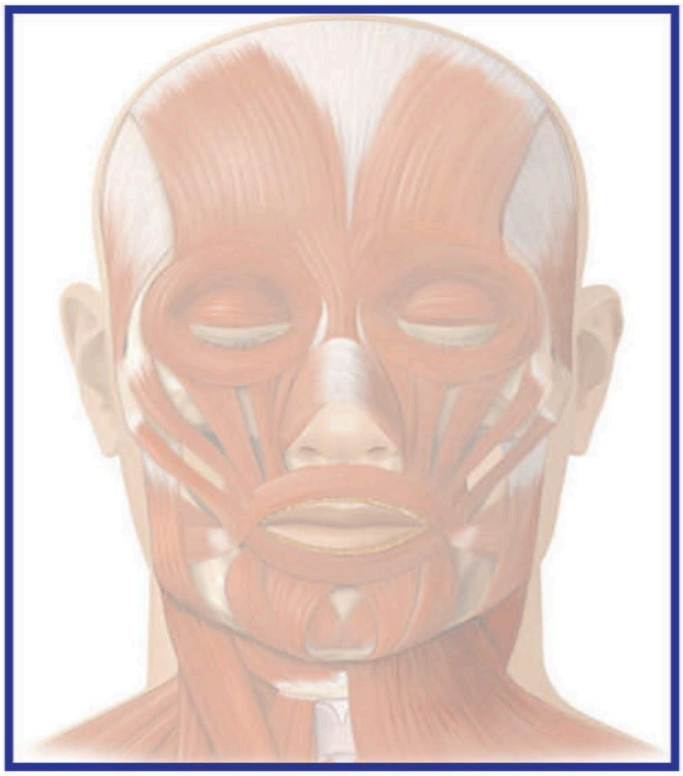
Medication Information

Lot Number

Expiration Date

Place Label Here

Injection Site Chart



Note: Please mark diagram (above) with number of units at each injection area as a history of the dosage per area. If touch-up treatments are performed please note original chart. This record is helpful for future treatments as it details the dosages per treatment area prior.

Total Units (Forehead) _____

Total Units (Glabellar) _____

Total Units (Crows Feet) _____(R) _____(L)

Total Units (Other Area) _____

TOTAL UNITS = _____

Remarks: _____

_____

_____

_____

Injector/Clinician Signature

Physician Signature

Botox Cosmetic® Treatment Form

Patient Name (Please Print)

Chief Complaint

Date of Service (Treatment)

Dilution Used

	Saline	# Units/1.0ml	# Units/0.1ml
○	1.0 cc	100 U/1.0ml	10 U/0.1ml
○	2.0 cc	50 U/1.0ml	5 U/0.1ml
○	2.5 cc	40 U/1.0ml	4 U/0.1ml
○	4.0 cc	25 U/1.0ml	2.5 U/0.1ml
○	5.0 cc	20 U/1.0ml	2 U/.01ml

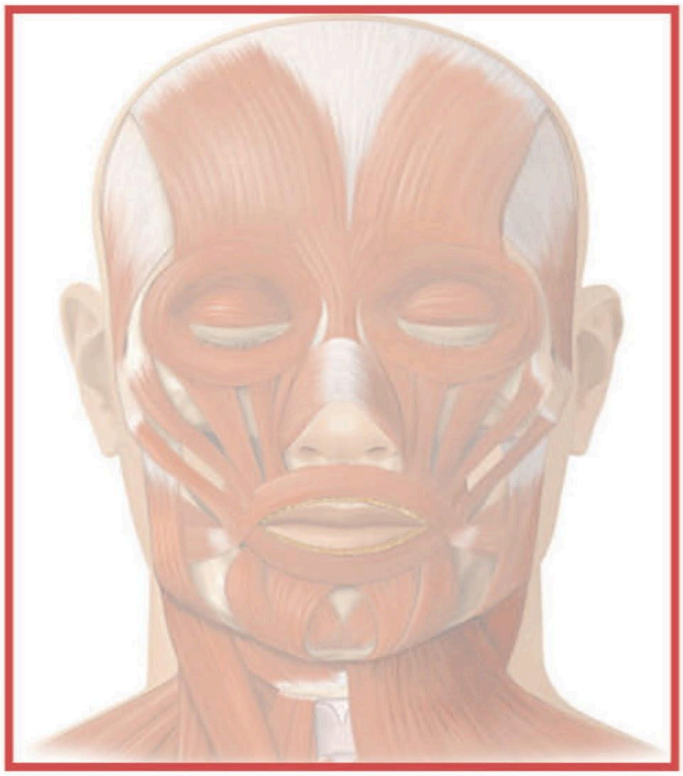
Medication Information

Lot Number

Expiration Date

Place Label Here

Injection Site Chart



Note: Please mark diagram (above) with number of units at each injection area as a history of the dosage per area. If touch-up treatments are performed please note original chart. This record is helpful for future treatments as it details the dosages per treatment area prior.

Total Units (Forehead) _____

Total Units (Glabellar) _____

Total Units (Crows Feet) _____(R) _____(L)

Total Units (Other Area) _____

TOTAL UNITS = _____

Remarks: _____

_____

_____

_____

Injector/Clinician Signature

Physician Signature

DERMAL FILLER TREATMENTS

CLINICAL POLICIES AND PROCEDURES

SECTION 2

PURPOSE

To ensure safe and effective treatment of clients undergoing dermal fillers administration at the **[INSERT PRACTICE NAME]**, the following policies and procedures have been developed. Dermal Fillers are defined as hyaluronic acid injectable products and hyaluronic acid injectable products with calcium hydroxyapatite (Radiesse).

POLICY

A Registered Nurse [RN], Physician Assistant or licensed medical personnel with current state licensure shall be able to assess, consult and treat clients with dermal fillers following the guidelines set herein. In the state of **[NAME OF STATE]**, the medical director or a physician assistant must perform a good faith examination prior to the use of dermal fillers.

SETTING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel can perform the administration of dermal fillers in various settings and locations, such as but not limited to:

- Physician Office
- Satellite clinic / health care office(s)
- MedSpa Setting authorized by the Medical Director
- Health Club Setting[3] authorized by the Medical Director

All dermal filler administration procedures shall be performed in a clean, safe environment, equipped with proper sharps disposal system, and universal precautions in place.

SUPERVISION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary.

All adverse reactions shall be reported immediately to the Medical Director. Adverse reaction(s) shall be documented in the client's chart.

PATIENT CONDITIONS

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will not knowingly treat any clients with a history of anaphylaxis, clients taking immunosuppressive medication, clients with infection over the injection area, or pregnant clients.

[3] California Business & Professions Code Section 2725 and California Code of Regulations, Section 1470-1474; Health Club Setting does not meet California performance standards. May apply in other states.

DERMAL FILLER ADMINISTRATION PROCEDURE

The Physician, Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

1. Complete assessment and a medical history questionnaire with all new clients.

2. Clients with a history of anaphylaxis, clients taking immunosuppressive medication, clients with infection over the injection area, or pregnant clients will be denied treatment.

3. Clients with a history of herpes simplex over the injection area must be pre-treated with acyclovir 400mg three times per day for 5 days and a further 2 days after treatment.

4. Upon passing medical screening, client will be fully informed of risks, benefits, and potential adverse reactions and an informed consent will be signed.

5. All dermal filler products will be stored and administered at room temperature.

6. Topical anesthesia (i.e. BLT prescription formulation) may be used 30 minutes prior to procedure.

7. Clients are injected while in upright seated position unless otherwise instructed for particular areas.

8. Client should remove any make-up from face and wash with mild soap and water. Swab treatment area with alcohol or other antiseptic.

9. Prior to administration the Registered Nurse [RN], Physician Assistant or licensed medical personnel will map out points of injection

10. Dermal Fillers are packaged for single use only. The needle is a 30 gauge needle. The needle is mounted on the syringe Luer-lock as per manufacturer instructions. The depth of injection is 1mm for superficial lines and 2mm for deeper lines.

11. Insert needle into the dermis at a depth of 1-2mm at an angle of 30 degrees parallel to the length of the wrinkle with the bevel facing upwards.

12. Prior to injecting product, aspirate the syringe to ensure that the needle was not placed into a vessel.

13. Inject slowly and retract, prior to exiting the skin with the needle - stop injecting.

14. No blanching should occur with the injection. If it does, stop the injection and massage the skin until it returns to its normal color.

15. Multiple injections should be placed serially along the length of the depression.

16. Massage the injected area to even out any lumps or bumps.

17. After the treatment, swab the area with hydrogen peroxide or alcohol and apply an ice-pack if patient is experiencing any discomfort.

18. When procedure is completed the client should be instructed to avoid strenuous exercise, sun exposure and alcohol for 24 hours.

19. Use of dermal fillers should be limited to 1.5 mL per treatment site or less.

RECORD KEEPING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall be responsible for maintaining client records, including but not limited to client assessment, signed informed consent of risks, benefits, and potential adverse effects, number of treatments, treatment sites, number of injections, solution/concentration used, and the client response to treatment.

Dermal Filler Patient History

Name: _____ Date: _____

Address: _____

Telephone: _____ Cell: _____

Date of Birth: _____

Consent signed: Yes No Date: _____

Previous Dermal Filler Yes No Date: _____

Complications: Yes No Date: _____

Type Dermal Fillers: _____

History of Anaphylactic Shock: Yes No Date: _____

History of Allergies: Yes No Date: _____

Medications

Asprin Yes No

Anti-Inflammatories Yes No

Anticoagulants Yes No

Steroids Yes No

Non-Steroidals Yes No
(i.e. Advil, Aleve, Celebrex)

_____

_____

Supplements

Ginko Biloba Yes No

Vitamin A Yes No

Vitamin E Yes No

Garlic Yes No

Flax Oil Yes No

_____

_____

Do you have at present, any history of the following medical conditions?

Have you had in the past, any history of the following medical conditions?

1. Multiple Severe Allergies Yes No

2. HX of Herpes around the Lips Yes No

3. Immunosuppressive Therapy Yes No

4. Autoimmune Disease Yes No

5. Other Medical History Yes No

(if you answered Yes to any one of the above please explain below)

Comments:

_____

_____

_____

_____

_____

I have answered the above questions to the best of my knowledge

.

_____ _____

Signature Date

Dental Infiltrate Consent

I, _____ understand that a Dental Infiltrate will be performed to provide temporary relief of discomfort associated with the administration of dermal filler. I understand that Dental Infiltrates are not 100% effective, but should reduce pain in most cases. The risks of a Dental Infiltrate include bleeding, infection, and adverse reaction to the anesthetic.

_____ (Initial) I do not have any hypersensitivity to any local anesthetic agents, nor do I have a history of malignant hyperthermia.

I have read and understand this consent and all of my questions have been addressed and answered to my satisfaction. I have no contraindicating factors, and thereby grant permission for a Dental Infiltrate. I certify that if any changes occur in my medical history/health or regime, that I will notify this office as soon as possible.

_____

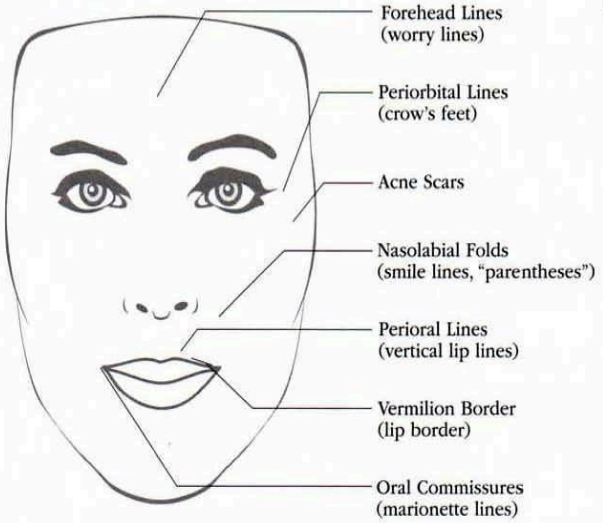
_____
Client (Print Name) Signature Date

_____

_____
Witness (Print Name) Signature Date

TREATMENT RECORD (SAMPLE)

INDICATE AREAS TREATED AND TREATMENT NOTES*



Notes: _____

TREATMENT RECORD

Date Treated *month/day/year*	Affix Lot Number Label	Area(s) Treated and Treatment Notes
	Affix label to patient chart. Apposer au dossier du patient. 1.0mL SAMPLE 00K131B / 5025A / 2005 - 10	❑ Forehead Lines ❑ Periorbital Lines ❑ Acne Scars ❑ Nasolabial Folds ❑ Perioral Lines ❑ Vermilion Border ❑ Oral Commissures ❑ Other: _____ Notes: _____
	Affix label to patient chart. Apposer au dossier du patient. 1.0mL SAMPLE 00K131B / 5025A / 2005 - 10	❑ Forehead Lines ❑ Periorbital Lines ❑ Acne Scars ❑ Nasolabial Folds ❑ Perioral Lines ❑ Vermilion Border ❑ Oral Commissures ❑ Other: _____ Notes: _____

*JUVÉDERM™ is not appropriate for every treatment area. JUVÉDERM™ is indicated for the treatment of moderate to severe facial wrinkles and folds.

M1126-02 1/07

TREATMENT RECORD (CONTINUED)

Date Treated *month/day/year*	Affix Lot Number Label	Area(s) Treated and Treatment Notes
	Affix label to patient chart. Apposer au dossier du patient. 1.0mL LOT NO. / CODE / EXP. DATE NO DE LOT / CODE DU PRODUIT / DATE DE PÉREMPTION 00K131B / 5025A / 2005 - 10 EXAMPLE	☐ Forehead Lines ☐ Perioral Lines ☐ Periorbital Lines ☐ Vermilion Border ☐ Acne Scars ☐ Oral Commissures ☐ Nasolabial Folds ☐ Other: ______ Notes: ______
	Affix label to patient chart. Apposer au dossier du patient. 1.0mL LOT NO. / CODE / EXP. DATE NO DE LOT / CODE DU PRODUIT / DATE DE PÉREMPTION 00K131B / 5025A / 2005 - 10 EXAMPLE	☐ Forehead Lines ☐ Perioral Lines ☐ Periorbital Lines ☐ Vermilion Border ☐ Acne Scars ☐ Oral Commissures ☐ Nasolabial Folds ☐ Other: ______ Notes: ______
	Affix label to patient chart. Apposer au dossier du patient. 1.0mL LOT NO. / CODE / EXP. DATE NO DE LOT / CODE DU PRODUIT / DATE DE PÉREMPTION 00K131B / 5025A / 2005 - 10 EXAMPLE	☐ Forehead Lines ☐ Perioral Lines ☐ Periorbital Lines ☐ Vermilion Border ☐ Acne Scars ☐ Oral Commissures ☐ Nasolabial Folds ☐ Other: ______ Notes: ______
	Affix label to patient chart. Apposer au dossier du patient. 1.0mL LOT NO. / CODE / EXP. DATE NO DE LOT / CODE DU PRODUIT / DATE DE PÉREMPTION 00K131B / 5025A / 2005 - 10 EXAMPLE	☐ Forehead Lines ☐ Perioral Lines ☐ Periorbital Lines ☐ Vermilion Border ☐ Acne Scars ☐ Oral Commissures ☐ Nasolabial Folds ☐ Other: ______ Notes: ______
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	Affix label to patient chart. Apposer au dossier du patient. 1.0mL LOT NO. / CODE / EXP. DATE NO DE LOT / CODE DU PRODUIT / DATE DE PÉREMPTION 00K131B / 5025A / 2005 - 10 EXAMPLE	☐ Forehead Lines ☐ Perioral Lines ☐ Periorbital Lines ☐ Vermilion Border ☐ Acne Scars ☐ Oral Commissures ☐ Nasolabial Folds ☐ Other: ______ Notes: ______
	Affix label to patient chart. Apposer au dossier du patient. 1.0mL LOT NO. / CODE / EXP. DATE NO DE LOT / CODE DU PRODUIT / DATE DE PÉREMPTION 00K131B / 5025A / 2005 - 10 EXAMPLE	☐ Forehead Lines ☐ Perioral Lines ☐ Periorbital Lines ☐ Vermilion Border ☐ Acne Scars ☐ Oral Commissures ☐ Nasolabial Folds ☐ Other: ______ Notes: ______

Post Treatment Form For Patients

After your treatment with dermal fillers, you might have some redness and swelling. This is normally less than seven (7) days.

1) Cold compresses may be used immediately after treatment to reduce swelling. If the inconvenience continues beyond seven (7) days or if other reactions or side effects occur, please contact the doctor.

2) Avoid touching the treated areas within six (6) hours following treatment. Do not massage the injection sites day of the injections. After that, the area can be gently washed.

3) You may shower and place make-up the following day.

4) Sunbathing and cold outdoor activities should be avoided until any redness or swelling disappears.

5) Avoid exercise and alcohol for six (6) hours after treatment.

6) Take anti-inflammatories if you have any pain; this should be enough. You might develop a headache as a consequence of the injections.

7) You might see some bruising occurring one (1) to two (2) days after injections at any of the injection sites. These will eventually go away in several days.

8) If you have previously suffered from facial cold sores, there is a risk that the needle punctures could contribute to a recurrence. Speak to the doctor about medications that may minimize a recurrence.

9) We generally like for you to return for a post injection appointment in five (5) to seven (7) days.

REQUIREMENTS FOR CLINICAL PERSONNEL

TRAINING / EDUCATION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall receive specialized training [and be certified] in the administration of DERMAL FILLERS. A Medical Doctor, Doctor of Osteopath, Advanced Practice Nurse experienced in this procedure, or a teaching institution specializing in this procedure, may perform this training and certification. The medical personnel performing these procedures must successfully complete the Dermal Filler Training Program for present products used and for products to be used in future periods.

COMPETENCIES & DOCUMENTATION

The Medical Director and/or [applicable licensure], shall

- Document [on the appropriate form] the initial evaluation and final determination recording satisfactory completion of training and competence.

- Evaluate of the competence of the Registered Nurse [RN], Physician Assistant or licensed medical personnel on an annual basis and/or as needed if indicated by client dissatisfaction or efficacy issues.

- The evaluation shall be maintained in the personnel file of the Registered Nurse, Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].

Informed Consent for Juvederm® Injections

INSTRUCTIONS
This is an informed consent document which has been prepared to help us inform you concerning Juvederm® (Non-Animal Stabilized Hyaluronic Acid, Allergan©) tissue filler injection therapy, its risks, and 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 this procedure.

INTRODUCTION
Juvederm® is a stabilized hyaluronic acid used to smooth moderate to severe facial wrinkles and folds around the nose and mouth or shape facial contours. Juvederm® has been FDA approved for the cosmetic treatment of moderate to severe facial wrinkles and soft tissue depressions. Hyaluronic acid is a naturally occurring substance that is found within all mammals. It is a material that is contained in various soft tissues. Hyaluronic acid can be synthetically produced from a process of bacterial fermentation, chemically stabilized, and purified for use as injectable soft tissue filler (non-animal, stabilized hyaluronic acid, Allergan©). The hyaluronic acid in Juvederm® is biocompatible and is a totally non-animal product; there is little risk of animal-based disease transmission or allergic reaction. Juvederm® injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the face and eyelid region, forehead, and lips. Juvederm® cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles and soft tissue depressions. Juvederm® injections may be performed as a singular procedure, in combination with other treatments such as BOTOX®, or as an adjunct to a surgical procedure. Juvederm® injections may require regional nerve blocks or local anesthetic injections or topicals to diminish discomfort. Soft tissue fillers, including Juvederm®, produce temporary swelling, redness, and needle marks, which resolve after a few days' time.

Continuing treatments are necessary in order to maintain the effect of Juvederm® over time. Juvederm® once injected will be slowly absorbed by the body. The length of effect for Juvederm® injections is variable.

ALTERNATIVE TREATMENTS
Alternative forms of management include not treating the skin wrinkles or soft tissue depressions by any means. Improvement of skin wrinkles and soft tissue depressions may be accomplished by other treatments: laser treatments, chemical skin-peels, or other skin procedures, alternative types of tissue fillers, or surgery such as a blepharoplasty, face or brow lift when indicated. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

RISKS OF JUVEDERM 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 based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences of Juvederm® injections.

Problems associated with the use of tissue fillers can relate to normal occurrences following tissue filler injections, or potential complications following tissue filler injections.

Bleeding and Bruising
It is possible, though unusual, to have a bleeding episode from a Juvederm® injection or local anesthesia used during the procedure. 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 Juvederm® injections.

Pain Discomfort
Pain Discomfort associated with Juvederm® injections is normal and usually of short duration. 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. Erythema (Skin Redness) in the skin occurs after injections. It can be present for a few days after the procedure. Needle Marks from the injections occur normally and resolve in a few days.

Acne-Like Skin Eruptions
Acneiform skin eruptions can occur following the injection of tissue fillers. This generally resolves within a few days.

Skin Lumpiness
Lumpiness can occur following the injection of Juvederm®. This tends to smooth out over time. In some situations, it may be possible to feel the injected tissue filler material for long periods of time.

Visible Tissue Filler Material
It may be possible to see any type of tissue filler material that was injected in areas where the skin is thin.

Asymmetry
The human face is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with tissue filer injections. There can be a variation from one side to the other in terms of the response to Juvederm® injection. This may require additional injections.

Skin Sensitivity
Skin rash, itching, tenderness and swelling may occur following Juvederm® injections. After treatment, you should minimize exposure of the treated area to excessive sun or UV lamp exposure and extreme cold weather until any initial swelling or redness has gone away. If you are considering laser treatment, chemical skin peeling or any other procedure based on a skin response after Juvederm® treatment, or you have recently had such treatments and the skin has not healed completely, there is a possible risk of an inflammatory reaction at the implant site.

Damage to Deeper Structures
Deeper structures such as nerves and blood vessels may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent.

Infection
Although infection following injection of tissue fillers is unusual, bacterial, fungal, and viral infections can occur. Herpes simplex virus infections around the mouth can occur following a tissue filler treatment. This applies to both individuals with a past 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 treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

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

Allergic Reactions and Hypersensitivity
As with all biologic products, allergic and systemic anaphylactic reactions may occur. Juvederm® 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. Allergic reactions may require additional treatment.

Scarring
Juvederm® should not be used in patients with known susceptibility to keloid formation or hypertrophic scarring. The safety of patients has not been studied.

Granulomas
Painful masses in the skin and deeper tissues after a Juvederm® injection are extremely rare.
Should these occur, additional treatments including surgery may be necessary.

Skin Disorders
Juvederm should not be used in areas with active inflammation or infections (e.g., cysts, pimples, rashes or hives). In rare instances, granuloma or abscess formation, localized necrosis and urticaria have been reported.

Antibodies to Juvederm
Presence of antibodies to hyaluronic acid tissue fillers may reduce the effectiveness of this material or produce a reaction in subsequent injections. The health significance of antibodies to hyaluronic acid tissue fillers is unknown.

Accidental Intra-Arterial Injection
It is extremely rare that during the course of injection, Juvederm® could be accidentally injected into arterial structures and produce a blockage of blood flow. This may produce skin necrosis in facial structures or damage blood flow to the eye, resulting in loss of vision. The risk and consequences of accidental intravascular injection of Juvederm is unknown and not predictable.

Under / Over Correction
The injection of soft tissue fillers including Juvederm® to correct wrinkles and soft tissue contour deficiencies may not achieve the desired outcome. The amount of correction may be inadequate or excessive. It may not be possible to control the process of injection of tissue fillers due to factors attributable to each patient's situation. If under correction occurs, you may be advised to consider additional injections of tissue filler materials.

Migration of Juvederm®
Juvederm® may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.

Drug and Local Anesthetic Reactions
There is the possibility that a systemic reaction could occur from either the local anesthetic or epinephrine used for sensory nerve block anesthesia when tissue filler injections are performed. This would include the possibility of light-headedness, rapid heartbeat (tachycardia), and fainting. Medical treatment of these conditions may be necessary.

Unsatisfactory Result
Juvederm® injections alone may not produce an outcome that meets your expectations for improvement in wrinkles or soft tissue depressions. There is the possibility of a poor or inadequate response from Juvederm® injection(s). Additional Juvederm® injections may be necessary.

Unknown Risks
The long term effect of Juvederm® beyond one year is unknown. The possibility of additional risk factors or complications attributable to the use of Juvederm as a soft tissue filler may be discovered.

Combination of Procedures
In some situations, Botox® injections or other types of tissue filler materials may be used in addition to Juvederm® in order to specifically treat areas of the face or to enhance the outcome from tissue filler therapy. The effect of other forms of external skin treatments (laser and other light therapies, microdermabrasion, dermabrasion, or chemical peels) on skin that has been treated with Juvederm® is unknown.

Pregnancy and Nursing Mothers
Animal reproduction studies have not been performed to determine if Juvederm® could produce fetal harm. It is not known if Juvederm® or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive Juvederm® treatments.

Drug Interactions
It is not known if Juvederm® reacts with other drugs within the body.

Long-Term Effects
Juvederm® injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the Juvederm® material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing Juvederm® treatment (injections) is necessary in order to maintain the effect of Juvederm. Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to Juvederm® injections.

HEALTH INSURANCE
Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same.

ADDITIONAL TREATMENT NECESSARY
There are many variable conditions in addition to risk and potential complications that may influence the long-term result of Juvederm® injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with Juvederm injections. There is no guarantee or warranty expressed or implied, on the results that may be obtained.

FINANCIAL RESPONSIBILITIES
The cost of Juvederm® injection may involve several charges. Additional costs of medical treatment would be your responsibility should complications develop from Juvederm® injections.

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). 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.

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.

I have read and understand the following Informed Consent Material for my specific procedure:
JUVEDERM®

The risks, benefits, and alternatives of the procedure(s) were explained to me. I understand the specific risks in the consent material for my surgery and understand the significant risks of bleeding, infection, blindness, injury to neighboring structures, capsule contracture(if implants involved), lumpiness, asymmetry, pulmonary emboli, deformity, skin loss or necrosis, healing problems, poor scars, loss of sensation(feeling), appearance/psychological changes, unsatisfactory result, need for future revision surgery and anesthesia. I understand the anticipated results and limitations of the surgery procedure(s).

The following instructions were explained to me:
Pre and Post procedure instructions, DVT prevention instructions, and medications to avoid instructions. I agree to follow all instructions, to follow up as directed, and to notify the office if any problems or questions arise.

_____ _____
Patient Signature Date Witness Print Name

_____ _____
Witness Signature Date Witness Address Line 1

INFORMED CONSENT–RESTYLANE® INJECTION

INSTRUCTIONS
This is an informed consent document which has been prepared to help your plastic surgeon inform you concerning Restylane® (Non-Animal Stabilized Hyaluronic Acid, Galderma/Medicis Aesthetics) tissue filler injection therapy, its risks, and 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 this procedure as proposed by your physician and agreed upon by you.

GENERAL INFORMATION
Restylane® is a stabilized hyaluronic acid used to smooth moderate to severe facial wrinkles and folds around the nose and mouth or shape facial contours. Restylane® has been FDA approved for the cosmetic treatment of moderate to severe facial wrinkles and soft tissue depressions.

Hyaluronic acid is a naturally occurring substance that is found within all mammals. It is a material that is contained in various soft tissues. Hyaluronic acid can be synthetically produced from a process of bacterial fermentation, chemically stabilized, and purified for use as an injectable soft tissue filler (non-animal, stabilized hyaluronic acid, Galderma/Medicis Aesthetics). The hyaluronic acid in Restylane® is biocompatible and is a totally non-animal product; there is little risk of animal-based disease transmission or allergic reaction. Restylane® injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the face and eyelid region, forehead, and lips.

Restylane® cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles and soft tissue depressions. Restylane injections may be performed as a singular procedure, in combination with other treatments such as BOTOX®, or as an adjunct to a surgical procedure. Restylane® injections require regional nerve blocks or local anesthetic injections to diminish discomfort. Soft tissue fillers, including Restylane®, produce temporary swelling, redness, and needle marks, which resolve after a few days.

Continuing treatments are necessary in order to maintain the effect of Restylane® over time. Restylane® once injected will be slowly absorbed by the body. The length of effect for Restylane® injections is variable.

ALTERNATIVE TREATMENTS
Alternative forms of management include not treating the skin wrinkles or soft tissue depressions by any means. Improvement of skin wrinkles and soft tissue depressions may be accomplished by other treatments: laser treatments, chemical skin-peels, other skin procedures, or alternative types of tissue fillers. Risks and potential complications are associated with alternative forms of medical or surgical treatments.

RISKS OF RESTYLANE® 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 based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences of Restylane® injections. Additional information concerning Restylane® may be obtained from the package insert sheets supplied by the manufacturer.

Problems associated with the use of tissue fillers can relate to normal occurrences following tissue filler injections, or potential complications following tissue filler injections, including Restylane®. Additional advisory information should be reviewed by patients considering tissue filler treatments that involve Restylane®.

Normal Occurrences during Tissue Filler Injections include:

Bleeding and Bruising
It is possible, though unusual, to have a bleeding episode from a Restylane® injection or local anesthesia used during the procedure. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment. 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 Restylane® 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.

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

Needle Marks
Visible needle marks from the injections occur normally and resolve in a few days.

Acne-Like Skin Eruptions
Acneiform skin eruptions can occur following the injection of tissue fillers. This generally resolves within a few days.

Skin Lumpiness
Lumpiness can occur following the injection of Restylane®. This tends to smooth out over time. In some situations, it may be possible to feel the injected tissue filler material for long periods of time.

Visible Tissue Filler Material
It may be possible to see any type of tissue filler material that was injected in areas where the skin is thin.

Asymmetry
The human face is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with tissue filler injections. There can be a variation from one side to the other in terms of the response to Restylane® injection. This may require additional injections.

Pain
Discomfort associated with Restylane® injections is normal and usually of short duration.

Skin Sensitivity
Skin rash, itching, tenderness and swelling may occur following Restylane® injections. After treatment, you should minimize exposure of the treated area to excessive sun or UV lamp exposure and extreme cold weather until any initial swelling or redness has gone away. If you are considering laser treatment, chemical skin peeling or any other procedure based on a skin response after Restylane® treatment, or you have recently had such treatments and the skin has not healed completely, there is a possible risk of an inflammatory reaction at the implant site.

RISKS OF RESTYLANE® INJECTIONS

Damage to Deeper Structures
Deeper structures such as nerves and blood vessels may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent.

Infection
Although infection following injection of tissue fillers is unusual, bacterial, fungal, and viral infections can occur. Herpes simplex virus infections around the mouth can occur following a tissue filler treatment. This applies to both individuals with a past 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 treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

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

Allergic Reactions and Hypersensitivity
As with all biologic products, allergic and systemic anaphylactic reactions may occur. Restylane® 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. Allergic reactions may require additional treatment.

Scarring
Restylane® should not be used in patients with known susceptibility to keloid formation or hypertrophic scarring. The safety of patients has not been studied.

Granulomas
Painful masses in the skin and deeper tissues after a Restylane® injection are extremely rare. Should these occur, additional treatments including surgery may be necessary.

Skin Disorders
Restylane® should not be used in areas with active inflammation or infections (e.g., cysts, pimples, rashes or hives). In rare instances, granuloma or abscess formation, localized necrosis and urticaria have been reported.

Antibodies to Restylane®
Presence of antibodies to hyaluronic acid tissue fillers may reduce the effectiveness of this material or produce a reaction in subsequent injections. The health significance of antibodies to hyaluronic acid tissue fillers is unknown.

Accidental Intra-Arterial Injection
It is extremely rare that during the course of injection, Restylane® could be accidentally injected into arterial structures and produce a blockage of blood flow. This may produce skin necrosis in facial structures or damage blood flow to the eye, resulting in loss of vision. The risk and consequences of accidental intravascular injection of Restylane® is unknown and not predictable.

Under /Over Correction
The injection of soft tissue fillers including Restylane® to correct wrinkles and soft tissue contour deficiencies may not achieve the desired outcome. The amount of correction may be inadequate or excessive. It may not be possible to control the process of injection of tissue fillers due to factors attributable to each patient's

situation. If under correction occurs, you may be advised to consider additional injections of tissue filler materials.

Migration of Restylane
Restylane may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.

Drug and Local Anesthetic Reactions
There is the possibility that a systemic reaction could occur from either the local anesthetic or epinephrine used for sensory nerve block anesthesia when tissue filler injections are performed. This would include the possibility of light-headedness, rapid heartbeat (tachycardia), and fainting. Medical treatment of these conditions may be necessary.

Unsatisfactory Result
Restylane® injections alone may not produce an outcome that meets your expectations for improvement in wrinkles or soft tissue depressions. There is the possibility of a poor or inadequate response from Restylane® injection(s). Additional Restylane® injections may be necessary. Surgical procedures or other treatments may be recommended in addition to Restylane® treatments.

Unknown Risks
The long term effect of Restylane® beyond one year is unknown. The possibility of additional risk factors or complications attributable to the use of Restylane as a soft tissue filler may be discovered.

Combination of Procedures
In some situations, Botox® injections or other types of tissue filler materials may be used in addition to Restylane® in order to specifically treat areas of the face or to enhance the outcome from tissue filler therapy. The effect of other forms of external skin treatments (laser and other light therapies, microdermabrasion, dermabrasion, or chemical peels) on skin that has been treated with Restylane® is unknown.

Pregnancy and Nursing Mothers
Animal reproduction studies have not been performed to determine if Restylane® could produce fetal harm. It is not known if Restylane® or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive Restylane® treatments.

Drug Interactions
It is not known if Restylane® reacts with other drugs within the body.

Long-Term Effects
Restylane® injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the Restylane® material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing Restylane® treatment (injections) is necessary in order to maintain the effect of Restylane®. Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to Restylane® injections. Future surgery or other treatments may be necessary. Restylane® injection does not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

ADDITIONAL ADVISORIES

Female Patient Information
It is important to inform your physician 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.

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 physician, 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.

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 sunblock or clothing coverage.

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 clotting and can cause more bleeding. These include non-steroidal anti-inflammatories such as Motrin, Advil, and Alleve. It is very important not to stop drugs that interfere with platelets, such as Plavix, which is used after a stent. It is important if you have had a stent and are taking Plavix that you inform the physician. Stopping Plavix may result in a heart attack, stroke and even 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 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.

Travel Plans
Any surgery holds the risk of complications that may delay healing and delay your return to normal life. Please let the physician 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.
-
Label FDA Issues
There are many devices, medications and injectable fillers that are approved for specific use by the FDA, but this proposed use is “Off-Label”, that is not specifically approved by the FDA. It is important that you understand this proposed use is not experimental and your physician believes it to be safe and effective.

Examples of commonly accepted “Off-Label” use of drugs or devices include the use of aspirin for prevention of heart disease, retinoids for skin care, and injection of botulinum toxin for wrinkles around the eyes.
____ I acknowledge that I have been informed about the Off-Label FDA status of Restylane® and I understand it is not experimental and accept its use.

HEALTH INSURANCE
Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Health insurance companies may not pay for Restylane® injections used to treat medical conditions. Please carefully review your health insurance subscriber information pamphlet.

ADDITIONAL TREATMENT NECESSARY
There are many variable conditions in addition to risk and potential complications that may influence the long

-term result of Restylane® injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with Restylane® injections. 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.

FINANCIAL RESPONSIBILITIES

The cost of Restylane injection may involve several charges. This includes the professional fee for the injections, follow-up visits to monitor the effectiveness of the treatment, and the cost of the material itself. It is unlikely that Restylane injections to treat cosmetic problems would be covered by your health insurance. 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 injections and will also be your responsibility. In signing the consent for this surgery/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.

___ I understand and unconditionally and irrevocably accept this.

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). 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 of the facts pertaining to 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.

I hereby authorize Dr._____ and such assistants as may be selected to perform the following procedure or treatment: RESTYLANE INJECTION (list the anatomic areas where Restylane will be injected)

1. I have received the following information sheet: INFORMED CONSENT – RESTYLANE INJECTION
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 understand what my surgeon can and cannot do, and I 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 of 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 treatment 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 physician's fees are separate from the anesthesia 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 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 (1-10). I AM SATISFIED WITH THE EXPLANATION.

_____
Patient or Person Authorized to Sign for Patient

Date_____

Witness _____

BELOTERO BALANCE®

Treatment Informed Consent

I _____, understand that I will be injected with

BELOTERO BALANCE Dermal Filler in the following areas: _____

_____.

BELOTERO BALANCE Dermal Filler is a resorbable hyaluronic-acid-based dermal filler approved by the United States Food and Drug Administration for the correction of moderate-to-severe facial wrinkles and folds, such as nasolabial folds.

Risks and complications that may be associated with BELOTERO BALANCE Dermal Filler and the injection procedure include, but are not limited to:

1. Facial Bruising, Redness, Swelling, Itching and Pain: I understand that there is a risk of bruising, redness, swelling, itching and pain associated with the procedure. These symptoms are usually mild and last less than a week, but can last longer. Patients who are using medications that can prolong bleeding, such as aspirin, warfarin, or certain vitamins and supplements, may experience increased bruising or bleeding at the injection site.

2. Nodules, and palpable material: I understand that there is a risk that small lumps may form under my skin due to the BELOTERO BALANCE filler material collecting in one area. I also understand that I may be able to feel the BELOTERO filler material in the area where the material has been injected. Any foreign material injected into the body may create the possibility of swelling or other local reactions to a filler material.

3. Accidental Injection into a Blood Vessel: I understand that BELOTERO BALANCE Dermal Filler can be accidentally injected into a blood vessel, which may block the blood vessel and cause damage of potentially large areas of distant tissue, or potentially even a heart attack, stroke or blindness.

4. Infection: As with all transcutaneous procedures, I understand that injection of any filler material carries the risk of infection.

5. History of Herpes Infection: I understand that there is a risk that injection of any filler material carries the risk of a recurrence of an outbreak of herpes (fever blisters/cold sores/shingles) and that the outbreak may be severe in nature. I have disclosed to the health care provider my medical history and, in particular, disclosed prior herpes outbreaks.

6. Allergic Reactions: I understand that BELOTERO BALANCE Dermal Filler should not be used in patients with severe allergies, a history of anaphylaxis, or history or presence of multiple severe allergies or hypersensitivity to any of the ingredients in BELOTERO BALANCE Dermal Filler, especially gram-positive bacterial proteins and hyaluronic acid.

7. Migration: I understand that BELOTERO BALANCE Dermal Filler, as with any filler material, may move from the place where it was injected.

8. Duration of Effect: I understand that the outcome of treatment with BELOTERO BALANCE Dermal Filler will vary among patients. In some instances, additional treatments may be necessary to achieve the desired outcome.

9. Concomitant Dermal Therapies: I understand that the safety of BELOTERO BALANCE Dermal Filler with concomitant dermal therapies such as epilation, UV irradiation, or laser, mechanical or chemical peeling procedures has not been evaluated in controlled clinical trials. If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with BELOTERO BALANCE Dermal Filler before the skin has healed completely, there is an increased risk of inflammatory reaction at the injection site.

10. Keloids/Scarring: I understand that the safety of BELOTERO BALANCE® Dermal Filler in patients with known susceptibility to keloid formation or hypertrophic scarring has not been studied.

11. Pregnancy/Age: I understand that the safety of BELOTERO BALANCE Dermal Filler for use during pregnancy, in breastfeeding females or in patients under 21 years of age has not been studied.

12. Recurrent Sore Throat/Osler Rendu: I understand that the safety of BELOTERO BALANCE® Dermal Filler in patients with known susceptibility to recurrent sore throat, or Osler Rendu endocarditis has not been studied.

13. Annual Treatment Volume: I understand that the safety of injecting BELOTERO BALANCE Dermal Filler in volumes greater than 6.0 mL per year has not been studied.

14. Interactions: I understand that the interaction of BELOTERO BALANCE Dermal Filler with drugs or other substances or implants has not been studied**.**

The above list is not meant to be inclusive of all possible risks associated with BELOTERO BALANCE Dermal Filler or dermal fillers in general, as there are both known and unknown side effects and complications associated with any medication or dermal filler injection procedure. I understand that medical attention may be required to resolve complications associated with my injection.

I understand that I should minimize exposure of the treated area to the sun, heat and extreme cold weather for approximately 24 hours after treatment or until any initial swelling or redness goes away and puncture sites have healed.

I have discussed the potential risks and benefits of BELOTERO BALANCE Dermal Filler with my health care provider. I understand that there is no guarantee of any particular results of any treatment.

I understand and agree that all services rendered will be charged directly to me, and I am personally responsible for payment. I further agree, in the event of non-payment, to bear the cost of collection, and/or court costs and reasonable legal fees, should they be required. By signing below, I acknowledge that I have read the foregoing informed consent, have had the opportunity to discuss any questions that I have with my doctor to my satisfaction, and consent to the treatment described above with its associated risks. I understand that I have the right not to consent to this treatment

and that my consent is voluntary. I hereby release the doctor, the person performing the BELOTERO BALANCE Dermal Filler injection and the facility from liability associated with this procedure.

_____	_____
Patient Signature Date	Witness Print Name
_____	_____
Witness Signature Date	Witness Address Line 1
	_____
	Witness Address Line 2

RADIESSE® Informed Consent

I, understand that I will be injected with RADIESSE Volumizing Filler in the following areas: .
RADIESSE® Volumizing Filler is a resorbable implant product approved by the United States Food and Drug Administration for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. Risks and complications that may be associated with RADIESSE Volumizing Filler and the implant procedure include, but are not limited to:

1. Facial Bruising, Redness, Swelling, Itching and Pain: **I understand that there is a risk of bruising, redness, swelling, itching and pain associated with the procedure. These symptoms are usually mild and last less than a week but can last longer. Patients who are using medications that can prolong bleeding, such as aspirin, warfarin, or certain vitamins and supplements, may experience increased bruising or bleeding at the injection site.**

2. Nodules, and palpable material: **I understand that there is a risk that small lumps may form under my skin due to the RADIESSE Filler material collecting in one area. I also understand that I may be able to feel the RADIESSE Filler material in the area where the material has been injected. Any foreign material injected into the body may create the possibility of swelling or other local reactions to a filler material.**

3. Nodules in Lips: **I understand that RADIESSE Volumizing Filler should not be injected in the lips. There are published reports of nodules associated with the use of RADIESSE Filler injected in lips.**

4. Migration: **I understand that the RADIESSE Volumizing Filler, as with any filler material, may move from the place where it was injected.**

5. Infection: **As with all transcutaneous procedures, I understand that injection of any filler material carries the risk of infection.**

6. History of Herpes Infection: **I understand that there is a risk that injection of any filler material carries the risk of a recurrence of an outbreak of herpes (fever blisters/cold sores/shingles) and that the outbreak may be severe in nature. I have disclosed to the health care provider my medical history and, in particular, disclosed prior herpes outbreaks.**

7. Allergic Reactions: **I understand that RADIESSE Volumizing Filler should not be used in patients with severe allergies, a history of anaphylaxis, or history or presence of multiple severe allergies or hypersensitivity to any of the ingredients in RADIESSE Filler.**

8. Keloids/Scarring: **I understand that the safety of RADIESSE Volumizing Filler in patients with known susceptibility to keloid formation or hypertrophic scarring has not been studied.**
9. Accidental Injection into a Blood Vessel: **I understand that RADIESSE Volumizing Filler can be accidentally injected into a blood vessel, which may block the blood vessel and cause local tissue damage, or potentially even a heart attack or stroke.**
10. Radio-opacity: **I understand that RADIESSE Volumizing Filler is radio-opaque and is visible on CT Scans and may be visible in x-rays.**

11. Duration of Effect: **I understand that the outcome of treatment with RADIESSE Volumizing Filler will vary among patients. In some instances, additional treatments may be necessary to achieve the desired outcome.**

12. Concomitant Dermal Therapies: **I understand that the safety of RADIESSE injectable implant with concomitant dermal therapies such as epilation, UV irradiation, or laser, mechanical or chemical peeling procedures has not been evaluated in controlled clinical trials. The application of laser or other energy-based treatments within weeks of RADIESSE treatment is not recommended as such treatments may alter the characteristics of RADIESSE injectable implant. If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with RADIESSE injectable implant, there is a possible risk of eliciting an inflammatory reaction at the implant site. This also applies if RADIESSE injectable implant is administered before the skin has healed completely after such a procedure.**

No studies of interactions of RADIESSE Volumizing Filler with drugs or other substances or implants have been conducted.

This above list is not meant to be inclusive of all possible risks associated with RADIESSE Volumizing Filler or dermal fillers in general, as there are both known and unknown side effects and complications associated with any medication or dermal filler injection procedure. I understand that medical attention may be required to resolve complications associated with my injection.

I understand that I should minimize exposure of the treated area to the sun or heat for approximately 24 hours after treatment or until any initial swelling or redness goes away. The safety of RADIESSE Volumizing Filler for use during pregnancy or in breastfeeding women has not been established.

I have discussed the potential risks and benefits of RADIESSE Volumizing Filler with my doctor. I understand that there is no guarantee of any particular results of any treatment. I understand and agree that all services rendered will be charged directly to me, and I am personally responsible for payment. I further agree, in the event of non-payment, to bear the cost of collection, and/or court costs and reasonable legal fees, should they be required. By signing below, I acknowledge that I have read the foregoing informed consent, have had the opportunity to discuss any questions that I have with my doctor to my satisfaction, and consent to the treatment described above with its associated risks. I understand that I have the right not to consent to this treatment and that my consent is voluntary. I hereby release the doctor, the person performing the RADIESSE Filler injection and the facility from liability associated with this procedure.

_____ _____

Patient Signature **Date**

DEVELOPMENT & APPROVAL OF STANDARDIZED PROCEDURE

The Clinical Policies and Procedures for the Administration of DERMAL FILLERS have been developed jointly by the Medical Director, Administrator, Advanced Practice Nurse and/or Registered Nurse. This procedure shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

_____ _____
Nurse Date

_____ _____
Medical Director Date

_____ _____
Administrator Date

PERSONNEL AUTHORIZED TO PERFORM PROCEDURE

NAME	DATE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____

COLLAGEN TREATMENTS

CLINICAL POLICIES AND PROCEDURES

SECTION 3

PURPOSE

To ensure safe and effective treatment of clients undergoing COLLAGEN REPLACEMENT THERAPY® administration at the **[INSERT PRACTICE NAME]**, the following policies and procedures have been developed.

POLICY

Nurse Practitioner, Physician Assistant or licensed medical personnel with current state licensure shall be able to assess, consult and treat clients with COLLAGEN REPLACEMENT THERAPY® following the guidelines set herein. In the state of California, the medical director or a physician assistant must perform a good faith examination prior to the use of any FDA Approved Collagen products.

SETTING

The Nurse Practitioner, Physician Assistant or licensed medical personnel can perform the administration of FDA Approved Collagen products in various settings and locations, such as but not limited to:

- Physician Office
- Satellite clinic / health care office(s)
- MedSpa Setting authorized by the Medical Director
- Health Club Setting[4] authorized by the Medical Director

All COLLAGEN REPLACEMENT THERAPIES shall be performed in a clean, safe environment, equipped with proper sharps disposal system, and universal precautions in place.

SUPERVISION

The Nurse Practitioner, Physician Assistant or licensed medical personnel shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary.

All adverse reactions shall be reported immediately to the Medical Director. Adverse reaction(s) shall be documented in the client's chart.

[4] California Business & Professions Code Section 2725 and California Code of Regulations, Section 1470-1474; Health Club Setting does not meet California performance standards. May apply in other states.

PATIENT CONDITIONS

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will not knowingly treat any clients with a history of anaphylaxis, allergy to lidocaine, clients taking immunosuppressive medication, clients with a history of connective tissue diseases such as rheumatoid arthritis, systemic lupus erythematous, polymyositis (PM), and dermatomyositis (DM), clients with infection over the injection area, or pregnant clients.

COLLAGEN REPLACEMENT THERAPY®PROCEDURE

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

- Complete assessment and a medical history questionnaire with all new clients.

17. Clients with a history of anaphylaxis, allergy to lidocaine, clients taking immunosuppressive medication, clients with a history of connective tissue diseases such as rheumatoid arthritis, systemic lupus erythematous, polymyositis (PM), and dermatomyositis (DM), clients with infection over the injection area, or pregnant clients will be denied treatment.

18. Clients with a history of herpes simplex over the injection area must be pre-treated with acyclovir 400mg three times per day for 5 days and a further 2 days after treatment.

19. Upon passing medical screening, client will be fully informed of risks, benefits, and potential adverse reactions and an informed consent will be signed.

20. Clients are injected while in a seated position.

21. Client should remove any make-up from face and wash with mild soap and water. Swab treatment area with alcohol or another antiseptic.

22. Prior to administration the Registered Nurse [RN], Physician Assistant or licensed medical personnel will map out points of injection

23. Adjust the plastic sleeve of the ADG needle so that the entire bevel is exposed to achieve 1mm depth for the collagen products (see manufacturer insert – some products may be at a depth of 2mm).

24. Insert into the dermis only until bevel is covered.

25. Inject slowly

26. Observe immediate blanching upon injection followed by a well pronounced wheal with FDA Approved Collagen products will produce a delayed blanch without a wheal.

27. If no blanching is observed, the placement of the needle is too deep. The needle should be withdrawn and the ADG needle reset.

28. Multiple injections should be placed serially along the length of the depression.

29. With any collagen injection, massage the injected area to even out any lumps or bumps.

30. After the treatment, swab the area with hydrogen peroxide or alcohol and apply an ice-pack.

31. When procedure is completed the client should be instructed to avoid strenuous exercise, sun exposure and alcohol for 24 hours.

RECORD KEEPING

The Nurse Practitioner, Physician Assistant or licensed medical personnel shall be responsible for maintaining client records, including but not limited to client assessment, signed informed consent of risks, benefits, and potential adverse effects, number of treatments, treatment sites, number of injections, solution/concentration used, and the client response to treatment.

REQUIREMENTS FOR CLINICAL PERSONNEL

TRAINING / EDUCATION

The Nurse Practitioner, Physician Assistant or licensed medical personnel shall receive specialized training [and be certified] in the administration of collagen products during COLLAGEN REPLACEMENT THERAPY®. A Medical Doctor, Doctor of Osteopath, Advanced Practice Nurse experienced in this procedure, or a teaching institution specializing in this procedure, may perform this training and certification.

COMPETENCIES & DOCUMENTATION

The Medical Director and/or [applicable licensure], shall

- Document [on the appropriate form] the initial evaluation and final determination recording satisfactory completion of training and competence.

- Evaluate of the competence of the Nurse Practitioner, Physician Assistant or licensed medical personnel on an annual basis and/or as needed if indicated by client dissatisfaction or efficacy issues.

- The evaluation shall be maintained in the personnel file of the Registered Nurse, Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].

DEVELOPMENT & APPROVAL OF STANDARDIZED PROCEDURE

The Clinical Policies and Procedures for the Administration of collagen products have been developed jointly by the Medical Director, Administrator, Advanced Practice Nurse and/or Registered Nurse. This procedure shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

_____ _____
Nurse Date

_____ _____
Medical Director Date

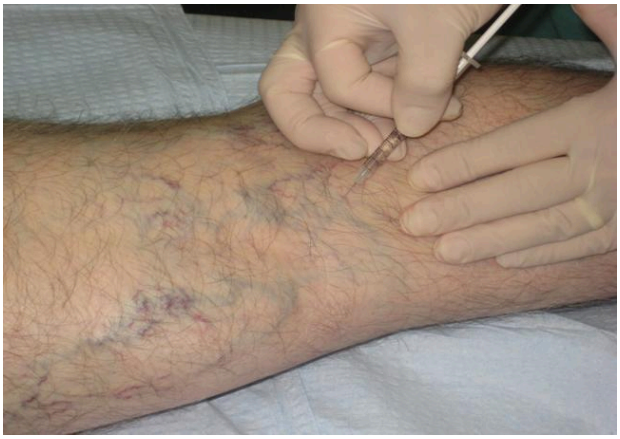
_____ _____
Administrator Date

PERSONNEL AUTHORIZED TO PERFORM PROCEDURE

NAME	DATE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____

COSMETIC SCLEROTHERAPY TREATMENTS

CLINICAL POLICIES AND PROCEDURES



SECTION 4

PURPOSE

To ensure safe and effective treatment of clients undergoing COSMETIC SCLEROTHERAPY administration at the **Enchanted Medical Aesthetics**, the following policies and procedures have been developed.

POLICY

A Registered Nurse [RN], Physician Assistant or licensed medical personnel with current state licensure shall be able to assess, consult and treat clients with SCLEROTHERAPY TREATMENT AND THERAPIES following the guidelines set herein. In the state of **Florida**, the medical director or a physician assistant must perform a good faith examination prior to the use of Asclera™ (POL), Sotradecal™ (Sodium Tetradecyl Sulfate), or Chromated Glycerin for the treatment of cosmetic, asymptomatic, reticular and telangiectasias of the body.

SETTING

The Nurse Practitioner, Physician Assistant or licensed medical personnel can perform the administration of SCLEROTHERAPY TREATMENT AND THERAPIES in various settings and locations, such as but not limited to:

- Physician Office
- Satellite clinic / health care office(s)
- MedSpa Setting authorized by the Medical Director
- Health Club Setting[5] authorized by the Medical Director

SCLEROTHERAPY TREATMENT AND THERAPIES administration procedures shall be performed in a clean, safe environment, equipped with proper sharps disposal system, and universal precautions in place.

SUPERVISION

The Nurse Practitioner, Physician Assistant or licensed medical personnel shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary.

All adverse reactions shall be reported immediately to the Medical Director. Adverse reaction(s) shall be documented in the client's chart.

[5] Business & Professions Code Section 2725 and California Code of Regulations, Section 1470-1474; Health Club Setting does not meet California performance standards. May apply in other states.

PATIENT CONDITIONS

The Nurse Practitioner, Physician Assistant or licensed medical personnel will not knowingly treat any clients with a history of anaphylaxis, allergy to lidocaine, clients taking immunosuppressive medication, clients with a history of connective tissue diseases such as rheumatoid arthritis, systemic lupus erythematous, polymyositis (PM), and dermatomyositis (DM), clients with infection over the injection area, pregnant clients or anyone determined to be “medically at risk”. In addition, a cursory examination of the proposed injection areas and lower extremities will be performed specifically locating any type of pre-ulceration, ulceration, pigmentation, protruding veins, or asymmetry (edema) in the lower extremities. All findings will be noted in the patient chart.

SCLEROTHERAPY PROCEDURE

Pre-Examination & Injection Procedures

Physical Examination of Lower Extremities (Feet)

- Look at skin tone and texture
- Look for regions of skin pigmentation
- Hair distribution on feet and toes
- Symmetry around ankles
    - Subtle signs of edema
- Assess pressure of veins
    - How quickly do they refill?
    - Palpate for any subtle bulging even in spider veins

Physical Examination of the Legs

- Medial, Anterior, and Posterior findings
    - Cosmetic vs. Medical
    - Any Bulging veins?
- Lateral Findings
    - Almost always cosmetic and low pressure!
- Groin and Abdomen
- Assess presence of both
    - Spider Veins (Telangiectasias)
    - Reticular Veins

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

1. Complete assessment and a medical history questionnaire with all new clients. Record complete patient medical history and medications. Any patient receiving or taking Coumadin or equivalent, has had a prior allergic reaction to sclerosants or recent or current DVT is absolutely contraindicated for treatment. Anyone with bulging veins (high pressure), Foot/Ankle findings of venous insufficiency, or failures of recent cosmetic sclerotherapy are contraindicated for treatment. Please refer to manufacturer's insert for additional contraindications for treatment.
2. Upon passing medical screening, client will be fully informed of risks, benefits, and potential adverse reactions and an informed consent will be signed.
3. **For Injection of Reticular Veins**
    - With skin prepped, bend needle at 20 degree angle with bevel up
    - Lay the hub of the needle on the skin with the needle FLAT
    - Advance the needle slowly and be prepared to aspirate
    - Advance slowly, watching for flashback
    - Once flashback seen, lock hub DOWN into skin
    - Inject proper amount of agent (0.5cc foam, 0.8cc liquid - estimates)
    - Second hand used to aspirate, not on skin, Assistant may need to hold illuminator

- Stop injection if wheal forms
- If unsure, re-aspirate during injection
- If using liquid, use a 1cc syringe, If using foam, a 3cc syringe works well
- A small amount of air in the hub can help you see the flashback.
- If the vein blows, try an adjacent segment.

4. For reticular veins the entire vein segment should blanch as the medicine is introduced and travels throughout the entire vein segment. If the entire vein segment is not fully sclerosed and you do not observe the complete blanching of the vein an additional injection will be needed for sclerosing the remaining vein.
5. Compression must be given by the of use cotton balls and tape over every treated reticular vein segment or by compressing each treated vein segment with gauze for about 5-10 seconds. There is no good study validating either approach. There is consensus agreement that patients wear Class I compression stockings after reticular vein treatments even for cosmetic sclerotherapy.
6. Other tips and understanding concerning the injection of reticular veins include if you see sclerosant flowing into adjacent telangiectasis, STOP your injection. Always try to inject the straightest segment of reticular veins and use gentle injection pressure and smaller volumes. Veins around the kneecap and behind the knee are especially prone to rupture, for kneecap reticulars, bend the knee at a 45 degree angle to stretch the skin.
7. **For Injection of Telangiectasis (Spider Veins)**
   - Begin this after reticular veins have been treated.
   - No aspiration or additional light visualization is needed.
   - Start from thigh and work down (Proximal to Distal).
   - Lay needle flat on skin, on top of straight vein segment.
   - Press DOWN and advance needle so tip catches skin.
   - Use second hand to hold skin taught
   - Advance needle while applying small amt. of pressure to plunger. Enter the vein “shooting” with positive injection pressure from syringe.
   - Once in vein, lock down and continue injecting slowly until no further visible blanch.
   - Both telangiectasia and reticulars in the same session
   - Keep track of sclerosant volumes not to exceed 10ml per session.
8. Compression is not necessary for telangiectasia.
9. Other tips and understanding concerning the injection of telangiectasis include If you get a visible wheal, STOP your injection. If you get wheals immediately on entering, you are injecting too forcefully. It’s OK to hold solution in the vein (with pressure on the plunger) once visible filling is complete. If veins are extensive, do just one leg at each session and small arterioles can commonly be injected in ankles. Allow 4 weeks for complete resolution.

SCLEROTHERAPY PRE/ POST TREATMENT INSTRUCTIONS

● Patient Pre-Treatment Instructions

- Let us know if you are taking any new medications or herbals.
- Remember to wear or bring shorts to each visit. Don't wear tight jeans.
- Bring your compression stockings to your visit.
- You may shave your legs the morning of your treatment, but do not use any lotions or moisturizers.
- Inspect your legs so you can point out the veins that bother you the most.

● Patient Post-Treatment Instructions

- If compression stockings were recommended, wear them! **DO** walk, and use your legs in a normal manner immediately after treatment. A 20-minute walk or bike ride every day can yield better results.
- **DO** continue your regular exercise program. **If you normally do any weight training or high-impact aerobics, postpone this for one week.**
- **DO NOT** expose your legs to the sun for at least 5 days. After that, always use at least an SPF 15 sunscreen. A sunburn after treatment will increase the risks of skin damage or ulceration.
- **DO NOT** shave your legs until the morning after the treatment (risk of infection).
- **AVOID** tub baths, saunas for one week after treatment.

NORMAL FINDINGS AFTER TREATMENT

- **At the injection sites:** Small "mosquito bites", reddish/brown bruising, or black and blue marks that change to a yellowish color are all normal. Bruising usually will fade within a week and should be completely gone in 2 weeks.
- **Along the treated veins:** There may be some mild discomfort. The vein may appear like it has not been injected at all, or may appear lighter. The veins can take up to 8 weeks to fade even when properly treated. The vein may feel hard or lumpy in places. This is also normal when larger veins are treated. A painful lump that is present 2 weeks after treatment is probably trapped blood. Trapped blood is caused when blood is stuck between two closed vein segments. It poses no health threat to you. It should be drained, however, to give the best cosmetic results. **If you think you have trapped blood, call us so we can see you to drain this areas before your next scheduled treatment.**

CALL US IF….

- You have severe leg pain or swelling. You have difficulty walking.

It took years for your veins to get this way, please
be patient and allow the time necessary to see your results!

SCLEROTHERAPY INFORMED CONSENT

FOR TREATMENT

I understand that medicine is not an exact science, and that though the vast majority of patients are satisfied with their results, there is no guarantee that I myself will be satisfied with the improvement of my veins after treatment. I acknowledge that the following topics have been fully explained to me, and that I understand the explanations I was given. I have had the opportunity to ask questions. I will be undergoing a vein removal procedure that involves the use of either laser application and or sclerotherapy. This consent form is provided as a means of education between the provider and the patient as to the methods and risks involved in vein removal. I understand that laser application and or sclerotherapy treatments may be repeated several times.

Methods/Options:

1. Prior to any procedure the physician will consult the patient.
2. The consultation time will allow for assessment of the problem, determination of a diagnosis and development of a treatment plan and what my options are if I chose to do nothing about my vein problem.
3. Diagnostic evaluations utilizing Doppler and or ultrasound may be required.
4. Treatments may include both Laser and or Sclerotherapy, using physician-determined appropriate energy levels and dosages.
5. The sclerosing agent, Asclera™ (Polidocanol), may be used in my procedure. Polidocanol is approved by the FDA and is widely used by many vein specialists in the United States and is considered by many specialists to be the safest sclerosing agent with the least amount of side effects
6. Photographs of the treatment area may be taken for the chart and for future comparison.

Risks:

1. Pain, burning, blister formation, and stinging sensation at the treatment site.
2. Infection associated with the treatment site.
3. Pigment(color) changes at the treatment site, including hyperpigmentation (increase in skin color or darkening).
4. Scar formation at the treatment site.
5. Poor cosmetic outcome.
6. Recurrence of vessels at the treated site.
7. Allergic reaction possibly severe or life-threatening.
8. Superficial or deep clot formation (deep vein thrombosis).
9. Bleeding and or bruising at the treatment site.
10. Ulcer formation at site of treatment.
11. Temporary phlebitis at the treatment site.
12. Matting (bruised appearance that is often temporary, but sometimes permanent)

Benefits:

1. Lightening of the veins in the treatment site.
- Complete removal of the veins in the treatment area.

I recognize that even though any particular problem may be extremely rare, it is always possible that any patient may have one of these problems. I accept that possibility for my own treatment. I understand that I am responsible for my own medical bills. I realize that most insurance companies do not cover treatment of spider veins and that I must pay for my treatment today. I authorize this practice to submit my bill to my insurance company and to receive reimbursement. If my insurance company reimburses this practice for the services in which I am paying for today I will receive a refund of payment from this practice.

Patient: _____ Date: _____

Witness: _____ Date: _____

I have discussed the above with the patient and have answered their questions.

Physician: _____ Date: _____

Asclera© (polidocanol) Injection Informed Consent

I, _____ understand that I will be injected with Asclera® (polidocanol) in the following areas:

_____

Asclera® (polidocanol) is a sclerosing agent indicated to treat uncomplicated spider veins (varicose veins ≤ 1 mm in diameter) and uncomplicated reticular veins (varicose veins 1 to 3 mm in diameter) in the lower extremity. It has not been studied in larger varicose veins > 3 mm in diameter.

Do not have Asclera® (polidocanol) Injection if you have a known allergy to Asclera® (polidocanol) or have an acute thromboembolic disease.

Risks and complications **that may be associated with Asclera® (polidocanol) Injection procedure include, but are not limited to:**

1. Anaphylaxis: **Severe allergic reactions have been reported following polidocanol use, including anaphylactic reactions, some of them fatal. Severe reactions are more frequent with use of larger volumes (>3 mL). The dose of polidocanol should therefore be minimized. Be prepared to treat anaphylaxis appropriately.**

2. Accidental Intra-arterial Injection: **I understand that Asclera® (polidocanol) can be accidentally injected into an artery, which may cause severe necrosis, ischemia, or gangrene.**

3. Inadvertent Perivascular Injection: **I understand that Asclera® (polidocanol) can be inadvertently injected near or around a vessel, which may cause pain.**

4. Injection site Necrosis: **I understand that there is a risk of necrosis at injection site. Severe adverse local effects, including tissue necrosis, may occur following extravasation.**

5. Injection site Thrombosis: **I understand that there is a risk of blood clot formation at the site of Asclera® (polidocanol) Injection.**

6. Injection site Neovascularization: **I understand that new blood cells may develop due to the trauma at the Asclera® (polidocanol) Injection site.**

7. Injection site Scar: **I understand that the Asclera® (polidocanol) Injection may cause a scar at the injection site.**

8. Bruising, Redness, Swelling, Itching, Pain, Warming, and Discoloration at injection site: **I understand that there is a risk of bruising, redness, swelling, itching and pain associated with the procedure. These symptoms are usually mild and last less than a week but can last longer.**

9. Injection site Irritation: **I understand that there is a risk of irritation associated with this procedure. As with any transcutaneous procedure, there may be the possibility of swelling or other local reactions.**

10. Pregnancy: **Asclera® (polidocanol) should not be injected in pregnant women. There are no adequate and well controlled studies in pregnant women. The effects of Asclera® (polidocanol) Injection on labor and delivery in pregnant women are unknown. It is not known whether polidocanol is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, Asclera® should not be used in nursing women. The safety and effectiveness of Asclera® in pediatric patients have not been established.**

Clinical studies of Asclera® did not include sufficient number of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Overdose may result in higher incidence of localized reactions such as necrosis.

- Post Market Safety Experience: **The following adverse reactions have been reported during use of polidocanol in world-wide experience; in some of these cases adverse events have been serious of troublesome. Because these reactions are reported voluntarily from a population of uncertain size and without a control group, it is not possible to estimate their frequency reliably or to establish a casual relationship to drug exposure.**
- Immune system disorders*:* **anaphylactic shock, angioedema, urticaria generalized, asthma**
- Nervous system disorders*:* **Cerebrovascular accident, migraine, paresthesia (local), loss of consciousness, confusional state, dizziness**
- Cardiac disorders*:* **Cardiac arrest, palpitations**
- Vascular disorders*:* **Deep vein thrombosis, pulmonary embolism, syncope vasovagal, circulatory collapse, vasculitis**
- Respiratory, thoracic and mediastinal disorders*:* **Dyspnea**
- Skin and subcutaneous tissue disorders*:* **Skin hyperpigmentation, dermatitis allergic, hypertrichosis (in area of sclerotherapy)**
- General disorders and injection site conditions*:* **Injection site necrosis, pyrexia, hot flush**
- Injury, poisoning and procedural complications*:* **Nerve injury**

No studies of interactions of Asclera® (polidocanol) Injection with drugs or other substances or implants have been conducted. This above list is not meant to be inclusive of all possible risks associated with Asclera® (polidocanol) Injection or sclerosing agents in general, as there are both known and unknown side effects and complications associated with any medication or sclerotherapy injection procedure. I understand that medical attention may be required to resolve complications associated with my injection.

I have discussed the potential risks and benefits of Asclera® (polidocanol) Injection with my doctor. I understand that there is no guarantee of any particular results of any treatment.

I understand and agree that all services rendered will be charged directly to me, and I am personally responsible for payment. I further agree, in the event of non-payment, to bear the cost of collection, and/or court costs and reasonable legal fees, should they be required. By signing below, I acknowledge that I have read the foregoing informed consent, have had the opportunity to discuss any questions that I have with my doctor to my satisfaction, and consent to the treatment described above with its associated risks. I understand that I have the right not to consent to this treatment and that my consent is voluntary. I hereby release the doctor, the person performing the Asclera® (polidocanol) Injection and the facility from liability associated with this procedure.

_____		_____	
Patient Signature	Date	Witness Print Name	
_____		_____	
Witness Signature	Date	Witness Address Line 1	

RECORD KEEPING

The Nurse Practitioner, Physician Assistant or licensed medical personnel shall be responsible for maintaining client records, including but not limited to client assessment, signed informed consent of risks, benefits, and potential adverse effects, number of treatments, treatment sites, number of injections, solution/concentration used, and the client response to treatment.

REQUIREMENTS FOR CLINICAL PERSONNEL

TRAINING / EDUCATION

The Nurse Practitioner, Physician Assistant or licensed medical personnel shall receive specialized training [and be certified] in the administration of collagen products during COLLAGEN REPLACEMENT THERAPY®. A Medical Doctor, Doctor of Osteopath, Advanced Practice Nurse experienced in this procedure, or a teaching institution specializing in this procedure, may perform this training and certification.

COMPETENCIES & DOCUMENTATION

The Medical Director and/or [applicable licensure], shall

- Document [on the appropriate form] the initial evaluation and final determination recording satisfactory completion of training and competence.

- Evaluate of the competence of the Nurse Practitioner, Physician Assistant or licensed medical personnel on an annual basis and/or as needed if indicated by client dissatisfaction or efficacy issues.

- The evaluation shall be maintained in the personnel file of the Registered Nurse, Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].

DEVELOPMENT & APPROVAL OF STANDARDIZED PROCEDURE

The Clinical Policies and Procedures for the Administration of collagen products have been developed jointly by the Medical Director, Administrator, Advanced Practice Nurse and/or Physician Assistant. This procedure shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

_____ _____
Nurse Date

_____ _____
Medical Director Date

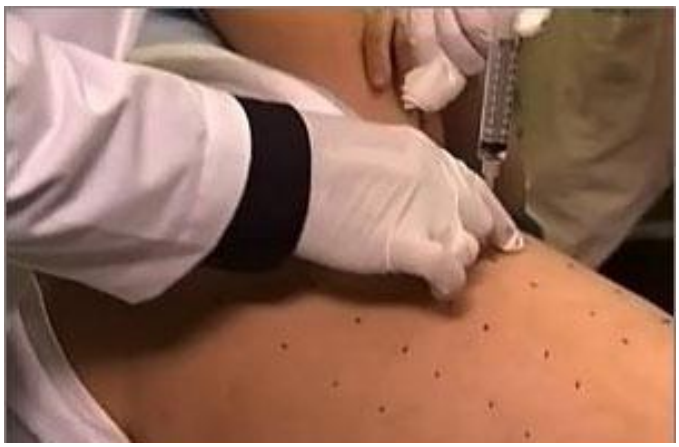
_____ _____
Administrator Date

PERSONNEL AUTHORIZED TO PERFORM PROCEDURE

NAME	DATE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____

MESOTHERAPY (LIPO-DISSOLVE) TREATMENTS

CLINICAL POLICIES AND PROCEDURES



SECTION 5

PURPOSE

To ensure safe and effective treatment of clients undergoing Mesotherapy or Lipo-Dissolve administration and treatments at the **[INSERT PRACTICE NAME]**, the following policies and procedures have been developed.

POLICY

A Registered Nurse [RN], Physician Assistant or licensed medical personnel with current state licensure shall be able to assess, consult and treat clients with Microdermabrasion following the guidelines set herein.

SETTING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel can perform the administration of Microdermabrasion in various settings and locations, such as but not limited to:

- Physician Office
- Satellite clinic / health care office(s)
- Medspa Setting authorized by the Medical Director
- Health Club Setting[6] authorized by the Medical Director

All Microdermabrasion procedures shall be performed in a clean, safe environment properly equipped with universal precautions in place.

SUPERVISION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary.

Adverse reactions such as bruising, swelling or infection shall be reported immediately to the Medical Director and shall be documented in the client's chart.

PATIENT CONDITIONS

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will not knowingly treat any clients with active herpes simplex blisters or cold sores.

PRECAUTIONS

Clients shall be advised of the following:

6

- Discontinue using certain topical agents [glycolic acids, alpha-hydroxy acids, Retin-A and Renova], for several days prior to microdermabrasion procedure.
- Remove contact lenses prior to treatment
- Certain facial skin disorders [acne, rosacea or telangiectasia] may be reason to not pursue treatment.
- If pronounced erythema [caused by sensitive skin] results, cease further treatments and seek re-evaluation from Medical Director.

Conditioning the skin prior to Microdermabrasion, is a critical factor in the overall outcome and resulting patient satisfaction [2 - 4 weeks is average]. The use of appropriate topical agents [except as noted above] can increase skin receptivity and responsiveness by reducing the stratum corneum barrier and by speeding up the skin's metabolism.

MESOTHERAPY/LIPO-DISSOLVE PROCEDURE

Pre-Examination & Injection Procedures

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

- Complete assessment and a medical history questionnaire with all new clients. Record complete patient skin history. Do not treat any patient who is medically at risk for any of the possible medical contraindications:
    - Active Cancer
    - Diabetes – especially insulin dependent
    - Liver Disease
    - Renal disease
    - HIV
    - Active skin infections in treated areas
    - Cardiac Problems (or related medications – anticoagulants)
    - History of scarring or pigmentation changes
    - Pregnancy or breast feeding

  Relative contraindications include:
    - Obesity
        - BMI over 30 (results will be poor at best)
        - OK for chin treatment (submental region)
    - Age under 21 (diet)
    - Inability to follow a Weight loss plan of ½ to 1 pound a week
        - High protein/low fat diet is required
    - Poor metabolism
    - Stress, lack of sleep or lack of exercise
    - Hypothyroid
    - Unrealistic expectations or distorted body image
    - Litigious personality
        - Unhappy with prior cosmetic procedures

- Upon passing medical screening, client will be fully informed of risks, benefits, and potential adverse reactions and an informed consent will be signed.

- Place patient in a relaxed supine position, remove from patient's skin any topical solutions or makeup, apply topical anesthesia to the appropriate areas of the skin for treatment (if appropriate). Remove any topical anesthesia before any treatment to the area.

- Mark patient elliptically over the desired treatment area and palpate areas of prominence over the area. Mark the patient for injection points using a surgical or other marking device defining the suggested dosing for each area. Suggested

spacing between injections is 1 – 2 inches apart evenly distributed through the entire elliptical pattern over the desired treatment area.

- Only the compounded medication PC/DC 50/42 is used for small fat pocket reduction. Use a 3cc or 5cc syringe utilizing a 30g ½ inch needle for the procedure.
- Using Point to Point (PPP) technique type of injections place the needle at a right angle to the skin at the marked areas for injection and inject to a depth of at least 6mm and not to exceed a depth of 13mm. Infiltrate each injection point with medication of .05cc to .8cc dependent upon fat mass or prominence.
- An estimate of 6 – 20 injections may be used for an 80sq cm area. Measure amount of solution injected and record area, injection points, and solution administered into patient treatment form. Do not inject more than (2) areas in any treatment session.
- Record into patient chart any post-procedure reaction including erythemia or any other skin reaction.
- Review with patient Mesotherapy Diet options (high protein/low fat) and the need to follow post procedure instructions.

Note:
The procedure listed above is for an initial treatment for small fat pocket reduction. The procedure requires multiple treatments dependent upon amount of area, fat mass, anatomical area, and other factors. Please refer to injection chart suggestions for further instruction. If the patient is returning for subsequent treatments please repeat the procedure using the same policy as listed above. Patients returning for additional treatments should have realized a change to the area and re-marking the patient and working in a smaller diameter area for treatment should be seen and injection pattern and area should be adjusted accordingly. The number of treatments needed for final resolution of fat prominence is between 2 and 8 dependent upon body part area and fat prominence.

Non-responders for mesotherapy/lipo-dissolve treatments typically are not following the diet and post procedure instructions. Other factors such as thyroid function, stressors or change in medications should also be researched and discussed with patients. It may also be possible that the injection amounts were inappropriate to realize the desired effect and may need to be titrated in a future treatment. Total solution that may be given to patients during a treatment may not exceed 30cc.

Body Area Estimation of Areas

- Always estimate for fat reduction treatments.
- Important for estimating treatment cost and amount of solution to be injected
- One “Body Area” is about the size of a typical sheet of paper.
- For treatment of localized fat, we cannot treat more than two body areas at the same treatment.

Acceptable Treatment Areas

- Chin & Jowels – 1 area (1-3 or more Treatments)
- Eye Pads – 1 area (1-2 Treatments)
- Arms – 1 area (2-5 Treatments)
- Armpit flank – 1 area (2-5 Treatments)
- Buffalo Hump – ½ area (2-5 Treatments)
- Abdomen – 1-1 ½ areas (3-8 Treatments)
- Bra Bulge area– ½ to 1 area (2-5 Treatments)
- Flanks– 1 area (2-3 Treatments)
- Love Handles– ½ to 1 area (2-5 Treatments)
- Hips– ½ to 1 area (2-5 Treatments)
- Thighs (Fat)– 1-2 areas (2-5 Treatments)
- Saddlebags– 1-1 ½ areas (2-3 Treatments)

Note:
Number of treatments is based upon patient BMI, amount of fat reduction, and the area of correction. Results vary by patient and the number of treatments is based upon estimates and may require less treatments for the desired effects.

Mesotherapy/Lipo-Dissolve Patient Informed Consent and Disclaimer

I am requesting that my health care professional perform Mesotherapy/Lipo-Dissolve, using Phosphatidylcholine (PPC) &/or other medications listed below, a form of Mesotherapy using subcutaneous injections, that will be referred to as the "Procedure" in the following. I am requesting the procedure be performed on (Choose Area) the sides of the abdomen, front of the abdomen, thighs, upper arm, chin, neck, infraorbital area (fat pad below the eyes), buttocks area, area between bra straps and underarms, above the knee;

(please state precise location)

_____

I have reviewed the Information Package for Meso/Lipo-Dissolve, and have discussed the Procedure that I am to receive with my health care professional. The nature of this Procedure, the possible complications and risks, as well as the possible benefits of the Procedure, the alternatives to the Procedure and the risks and benefits for those alternatives have been explained to me in language and using terminology that I understand. My health care professional has personally answered all of my outstanding questions about the procedure.

I fully understand that this Procedure is an elective aesthetic procedure, and that there is no emergency medical condition that requires that I have the Procedure. Neither my health care professional nor the staff has made any promises or warranties or guarantees as to the success or effectiveness of the Procedure.

I understand that the Procedure may not be effective. I have been advised that I may need several procedures for this Procedure to be effective.

I understand that after the Procedure, I may experience side effects such as pain, discomfort and tingling, burning, swelling, bruising, which may be temporary or permanent. I am aware that I may experience dizziness and I will notify my health care professional and agree to lie down as instructed. I have been advised that I may find some of these side effects difficult to tolerate.

I understand that there are numerous risks and complications, both known and unknown, connected with the Procedure. These can include by not be limited to infections that can be localized or could spread throughout my body, hemorrhage or bleeding, delayed healing, under or over correction and other risks and complications, that are unknown at this time.

I understand that the Procedure is a relatively new procedure and that little is known about its long-term safety and effectiveness.

I understand that the Procedure does not correct certain health problems including but NOT limited to Diabetes, heart attack or stroke, blood clots, lung problems, stomach or intestinal problems, or bladder disease.

I understand that the field of Meso/Lipotherapy is continuing to evolve and that if I were to postpone my Procedure there is the possibility that new procedures and ingredients of

Meso/Lipotherapy might be improved or some other procedure might become available.

I understand that I will need certain post-Procedure care. I will be dutifully responsible in being strictly compliant with the recommendations from my health care professional that may include, but are not limited to ice and compression dressings, etc. I must immediately report any unusual symptoms, know to me, to my health care professional and be especially aware of any slight nature or prominence of persistent chills or fever, redness or increased warmth, excessive bruising or swelling at the site of the injection, fatigue, lethargy, decreased appetite, jaundice (yellowing of skin or the whites of the eyes), dark urine, unusual severe itchiness or abdominal pain.

I give my healthcare professional permission to use data about my treatment for research purposes. I understand that my name and personal identifying information will remain confidential, unless I give written permission to disclose this information. I give my healthcare professional permission to photograph the procedure.

I understand that Phosphatidylcholine (PPC) is being used in an “off label” use and is not approved by the Federal Drug Administration (FDA). I have decided that the benefits of this form of Meso/Lipotherapy outweigh the potential for complications. I am of clear mind and completely understand the nature of the Procedure and ANY and all possible risks mentions, but NOT limited to all stated risks, which are related to the Procedure.

By signing below, I am indicating that I have read and understood the information in this Patient Consent Form, that I have been verbally advised about the Procedure, that I have had an adequate and reasonable opportunity to ask questions, that I have received all the information I desire concerning the Procedure, all of this information is mentally and physically clear to me, and that I authorize and consent to the performance of the Procedure. I release from all liability the medical professional performing this procedure as well as the facility where it is being done.

_____

Patient Signature Printed Name Date

_____

Witness Printed Name Date

Mesotherapy Pre-Treatment Instructions

- **Avoid** Willow Bark or Gingko Biloba supplements for at least 10 days prior to treatment.
- **Avoid** Aspirin, Vitamin E, anti-inflammatory drugs such as Motrin, Advil, or Aleve for at least 5 days prior to treatment.
- Try to **limit caffeine intake** in the 24 hours before your treatment.
- If you take any prescription stimulants, **do not take them** on the day of treatment.
- If you are being treated on the face, start your Medrol dose pack 3 days before treatment. On the **morning** of your treatment.
- Wash the area to be treated vigorously with antibacterial soap.
- Do not use any lotions, creams, bath oils, or sprays on the areas to be treated.
- Apply your Arnica cream (except if treated on the face) 2+ hours before treatment.
- Eat a **light, high-protein** meal 2-4 hours before your treatment. A **high protein bar** (with 30 grams protein or more) approx. 30-45 min. before your treatment can really help.

Mesotherapy Post-Treatment Instructions

- You may go back to work.
- **Avoid hot baths** or showers for at least 48 hours.
- Drink **1 Gallon of water the day of your treatment** and at least **80 ounces of water (10 glasses) a day until all your treatments are finished.**
- **No hot tubs** (over 102 degrees) or saunas for at least two weeks after your treatment.
- **No vigorous exercise** for 48 hours.
- **Continue to use your Arnica cream** 3-4 times a day for the next 2-3 days.
    - **Do not** use any other creams or lotions on the treated areas for 48 hours.
- Wear **loose fitting clothes** for at least 48 hours after your treatment
- **Remember, bruising may last for 10 days or more after treatment.** Avoiding the drugs and herbals mentioned above helps reduce bruising.
- **Avoid** even casual sunbathing for 48 hours. After then, use at least an SPF 30 sunscreen whenever treated areas are exposed to any sunlight for two weeks after the procedure. Do not sunbathe intensely or use tanning beds during these two weeks.

If your treatment was on the face, finish your Medrol dose pack and take your Lasix as directed.

Sample Mesotherapy Diet

High Protein / Low Fat Diet

- Any high protein/low fat diet can be used
- 25gm high protein, low fat meals on day of treatment.
    - Consider protein shake or bar before treatment.
- 72 ounces of water per day
    - Restrict caffeine intake
- Low-carb, low saturated fat diet designed to lose ½ pound a week

Tips: PC/DC Lipotherapy

- Poor Responders
    - Are they following the diet?
    - Any new stressors or medications? Getting enough sleep?
    - Enough volume of agent given to treated areas?
    - Too many areas being done at once?
- Alternative formulation
    - Add L-Carnitine and/or Aminophylline 1-2cc per 10cc syringe
        - Tachycardia and flushing is possible using Aminophylline. Use with caution!
    - 5cc PC 100mg/DC 84mg mixture
    - 1-2cc L-carnitine
    - 1-2cc Aminophylline
    - 1cc 2% Lidocaine or Procaine
    - Normal saline to complete the 10cc syringe

DEVELOPMENT & APPROVAL OF STANDARDIZED PROCEDURE

The Standardized Procedure and Protocol for the Administration of Mesotherapy (Lipo-dissolve) treatment has been developed jointly by the Medical Director, Administrator, and the Registered Nurse. This protocol shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

_____ _____
Nurse Date

_____ _____
Medical Director Date

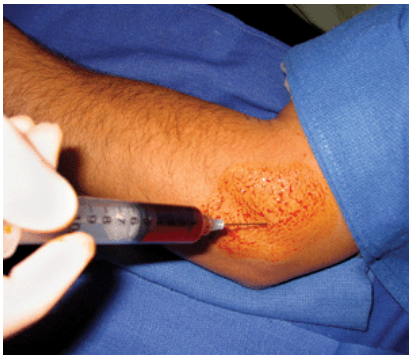
_____ _____
Administrator Date

PERSONNEL AUTHORIZED TO PERFORM PROCEDURE

NAME	DATE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____

PLATELET RICH PLASMA (PRP) TREATMENTS

CLINICAL POLICIES AND PROCEDURES



SECTION 6

PURPOSE

To ensure safe and effective treatment of clients undergoing Platelet Rich Plasma administration and treatments at the **[PRACTICE NAME]**, the following policies and procedures have been developed.

POLICY

A Registered Nurse [RN], Physician Assistant or licensed medical personnel with current state licensure shall be able to assess, consult and treat clients with Platelet Rich Plasma treatments following the guidelines set herein.

SETTING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel can perform the administration of Microdermabrasion in various settings and locations, such as but not limited to:

- Physician Office
- Satellite clinic / health care office(s)
- Medspa Setting authorized by the Medical Director
- Health Club Setting[7] authorized by the Medical Director

All Platelet Rich Plasma procedures shall be performed in a clean, safe environment properly equipped with universal precautions in place.

SUPERVISION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary.

Adverse reactions such as bruising, swelling or infection shall be reported immediately to the Medical Director and shall be documented in the client's chart.

PATIENT CONDITIONS

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will not knowingly treat any clients with active herpes simplex blisters or cold sores.

PRECAUTIONS

Clients shall be advised of the following:

[7]

- Confirmation that analgesics (NSAIDS) or anxiolytics prior to the treatment.
- Consultation with patient along with informed consent prior to initiation of treatment.
  - Medical “At Risk” conditions
  - Platelet dysfunction syndrome
  - Critical thrombocytopenia
  - Hemodynamic instability
  - Septicemia or local infection to injection site
- Possible contraindications are reviewed including change in medications.
  - NSAIDs use within (48) hours of procedure
  - Corticosteroid injection at treatment site (1 month)
  - Systemic use of corticosteroids (2 weeks)
  - Cancers (hematopoietic or bone)
  - HGB < 10g/dl or platelet count < 105/ul

Patient shall be well hydrated to ensure a proper blood draw for the procedure, eating a light meal prior to the procedure is encouraged. Medical healthcare professional authorized to perform the blood draw from patient will evaluate the veins for the blood draw. Any issues concerning the collection of blood from the patient will be discussed, evaluated and if necessary contacting the Medical Director for further guidance and instruction. Any patient that has any prevailing symptoms or is contraindicated for the procedure will not be given the procedure.

Platelet Rich Plasma (PRP) Treatment for Hair Loss

Platelet Rich Plasma (PRP) is an injection treatment that uses the components of a person's own blood to stimulate hair growth.

Platelets are very small cells in your blood that are involved in the clotting process. When PRP is injected into the damaged area it causes a mild inflammation that triggers the healing cascade.
As the platelets organize in the tissue they release a number of enzymes to promote healing and restoration of tissue. They have also been shown anecdotally to promote hair growth

Method
A small quantity of blood (30cc-50cc) is drawn from the patient into a syringe. This is a relatively small amount compared to blood donation which removes approximately up to 500cc. The blood is spun in a special centrifuge (according to standard Harvest Technologies) to separate its components (Red Blood Cells, Platelet Rich Plasma, and Plasma) A second spin is required to achieve optimal concentration.

The platelet rich plasma is separated from the rest of the blood and then activated with a small amount of calcium to allow the release of growth factors from the platelets which in turn amplifies the healing process. Following the administration of local anesthesia (xylocaine), PRP is then injected directly into thinning areas of the scalp.

Treatment Schedule
· 1st Rx
· 2nd Rx at 12 weeks (if necessary – depending upon the response)
· 3rd Rx at 24 weeks (if necessary)
· As needed

Indications
· Androgenetic hair loss (male and female pattern alopecia)
· Age ≥ 21 years

Contraindications
· Acute and chronic infections
· Certain skin diseases (i.e. SLE, porphyria)
· Allergies to anesthetics
· Cancers
· Chemotherapy
· Blood or bleeding disorders
· Anti-coagulation therapy
· Chronic liver disease

· Systemic use of corticosteroids within two weeks of the procedure
· Pregnant or breast feeding

Risks and Complications
· Pain or itching at the injection site
· Bleeding, bruising, swelling and/or infection
· Temporary pinkness/redness (flushing) of the skin
· Allergic reactions to the solution
· Injury to a nerve from the injection
· Nausea
· Peri-operative dizziness or fainting

Photographs
I authorize the taking of clinical photographs for historical, training, and/or promotional purposes. I understand confidentiality will be maintained.

Consent
My consent and authorization for this elective procedure is strictly voluntary. By signing this informed consent form, I hereby grant authority to the physician/practitioner to perform Platelet Rich Plasma (PRP) injections to area (s) discussed during our consultation.

I have read this informed consent and certify I understand its contents in full. All of my questions have been answered to my satisfaction and I consent to the terms of this agreement.
I agree to adhere to all safety precautions and instructions after the treatment. I understand that medicine is not an exact science and acknowledge that no guarantee has been given or implied by anyone as to the results that may be obtained by this treatment.

I understand this procedure is “elective” and not covered by insurance and that payment is my responsibility. Any expenses which may be incurred for medical care I elect to receive outside of this office, such as, but not limited to dissatisfaction of my treatment outcome will be my sole financial responsibility. Payment in full for all treatments is required at the time of service and is non-refundable.

I hereby give my voluntary consent to this PRP procedure and release [**Insert Practice Name**] and its staff from liability associated with the procedure. I certify that I am a competent adult of at least 21 years of age. I understand that if I have questions or concerns regarding my treatment, I will notify this office at [**Insert Telephone Number**] so that timely follow-up and intervention can be provided.

_____
Patient Name (print)

_____
Patient Signature/Date

_____
Physician Name (print)

_____
Signature/Date

PLATELET RICH PLASMA (PRP) INFORMED CONSENT

I _____ have been advised and consulted about the injection technique of platelet rich plasma.

I have been advised that platelet rich plasma is an established treatment techniques used to tighten and strengthen weak and damaged ligaments and tendons which are believed to cause pain and instability. It is also used to decrease pain and improve function in some forms of arthritis.

The technique requires the injection of Platelet Rich Plasma derived from my own blood according to standard blood collection and injection techniques. The site of injection is where the ligament or tendon attaches to the bone, at the joint capsule, or inside the joint.

I have been informed that the procedure has been used on many patients and has been proven safe. The procedure may initially increase the painful area or reproduce symptoms for one to three days (and occasionally, as long as ten days), and then may decrease in intensity, but may not completely eliminate my symptoms.

I understand that some insurance companies have determined this treatment to be experimental due to the lack of large research studies in the scientific literature. I understand the benefits of the procedure are improved or resolved pain and improved function.

I have been informed that the alternatives to PRP are:

- Do nothing
- Surgical intervention may be a possibility
- Injection with steroids (not long lasting results)
- Manipulation may provide temporary pain relief
- Acupuncture

I have been informed that the risks and complications of PRP are:

- Immediate pain at the injection site
- Stiffness in the injected joint
- Bruising
- Allergic reaction
- Infection
- Nerve or muscle injury
- Nausea
- Dizziness or fainting
- Swelling after joint injections

- Bleeding
- Temporary blood sugar increase
- Itching at injection site

I have been informed that the risks of not having treatment are:
- No relief of pain
- Continued instability of the damaged joint or ligament and probable worsening of pain.

I HAVE READ (OR HAVE HAD READ TO ME) THE ABOVE CONSENT. [**INSERT PRACTICE NAME**] HAS EXPLAINED THE PROCEDURE(S) TO ME SO THAT I FULLY UNDERSTAND IT (THEM). NO GUARANTEE OF SUCCESSFUL TREATMENT HAS BEEN IMPLIED. I UNDERSTAND THAT I AM ENTITLED TO A COPY OF THIS CONSENT FORM UPON REQUEST.

I understand that this procedure is usually not covered by insurance and I am responsible for the total charges.

_____ _____
Parent or Legal Guardian Date

_____
Patient Signature

_____ _____
Witness Date

_____
Representative [**Practice Name**]

PLATELET RICH PLASMA TREATMENTS

Sample Protocol

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

- Complete assessment and a medical history questionnaire with all new clients. Record complete patient skin history. Do not treat any patient who is being treated with Accutane, a period of (6) months must elapse before applying any acid to the skin. Pregnancy is contra-indicated.

- Upon passing medical screening, client will be fully informed of risks, benefits, and potential adverse reactions and an informed consent will be signed.

- Secure patient's hair and cleanse area, patient is in a relaxed supine position and apply eye shield for facial rejuvenation procedures for the entire procedure.

- Remove from patient's skin any topical solutions or makeup, apply topical anesthesia to the appropriate areas of the skin for treatment. Only larger needle depth treatments (>.5mm) require anesthesia, please see table 1.0 for needle sizing chart and appropriate areas of treatment.

- Use appropriate amount of topical anesthesia (BLT Formulation – 8/12/8), wait until face is anesthetized (typically 5-10 minutes) and remove the formulation from the skin with alcohol or witch hazel.

- Apply topical solution to the prospective treated area; suitable topical solutions may include platelet rich plasma from patient, platelet poor aspirate from patient, un-crosslinked HA, sterile glycol based topicals, DMAE and Absorbic Acid topical, or any other topical as instructed by the physician.

- **Dermal rollers** are only indicated for behind the thighs for cellulite or for dimpling of the buttocks area. Dermal rollers may also be used for acne scarring or skin pleating of the cheeks only and is by the direction of the physician. Dermal rollers are for single patient use only and must be discarded after treatment into the appropriate biohazard sharps container.

- The [enter product name] skin needling system (aka needle pen) is indicated for all body part areas and conditions in Table 1.0 but may not be as effective for treatment as compared to (7) indicated uses for dermal rollers. The physician or other supervising medical professional will prescribe which system to use.

- The protocol for cellulite of the thighs and dimpling of the buttocks using a dermal rollers will be (7) passes or more of the device over the treated area quickly as patient's will find comfort if the procedure is done in a timely manner. Additional passes of the device (> 7) may be considered and will be based upon patient

discomfort levels. Cross hatching of the direction of the strokes and speed of the strokes are encouraged for better results. Please see Table 1.0 for sizing chart for dermal roller size.

- The protocol for acne of the mid-face area (cheeks) using a dermal rollers will be (4) passes or more of the device over the treated area quickly as patient's will find comfort if the procedure is done in a timely manner. Additional passes of the device (> 4) may be considered and will be based upon patient discomfort levels. Again, cross hatching of the direction of the strokes and speed of the strokes are encouraged for better results. Please see Table 1.0 for sizing chart for dermal roller size.

- If using the [enter product name] skin needling system (aka needle pen) the protocol will be (4) passes or more of the device over the treated using a circular pattern. The device should be resting on the skin and no pressure given other than allowing the head of the device to gently glide over the skin in a circular motion. Additional passes of the device (> 4) may be considered and will be based upon patient discomfort levels. The needle heads of the device will be discarded after treatment into the appropriate biohazard sharps container. Changing of the needle heads is encouraged when treating larger body areas or large areas of the face. Do not exceed specifications set forth in Table 1.0.

- **Note:** Patient may experience pin point bleeding if using larger needle heads or dermal rollers, erythema and uncomfortable some tightness at this point and may be slightly anesthetized to a light touch for up to 30 minutes.

- Apply Moisturizer or Hydration Lotion to all treated areas.

- Apply Sun Block or appropriate topical moisturizer, Discuss the importance of maintaining the treatment results with the appropriate skincare maintenance products. The next appointment will be scheduled per treatment schedule accordingly.

- If patient is returning for additional treatment from the series of treatments prescribed you must evaluate the patient from the prior visit, follow-up visits are scheduled at (2) to (4) week intervals. Access the indications for delayed healing, ulceration or hypertrophic scarring conditions to the area treated. If the presence of any of the preceding conditions have occurred, all treatments will be terminated and will be reported to the medical director or residing physician for further instruction. No other treatments may be applied without evaluation.

Sanitation and Health Safety Protocol

- All implements that come in contact with human skin and/or a mucus membrane should be sanitized in Bio-Tech or alcohol.
- Microdermabrasion is not recommended for use with BHA and/or Sal
- All persons giving a treatment should never come in contact with the recipient's skin and/or mucus membrane; gloves should be worn at ALL times.
- Gloves should be worn while handling all chemicals and acids, as repeated exposure can cause injury to the person performing the procedure.
- Any instruments used to puncture the skin should be placed in a sharps container immediately after use.
- Any disposable implements such as cotton tip swabs, gauze, cotton rounds, and tongue depressors, used during the procedure should be disposed of immediately after the procedure. If any of these implements come in contact with bodily fluids, they are to be disposed of in a Bio-Hazard container and/or bag.

Table 1. Suggested Dosing and Needle Placement Methods for Aesthetic Indications:

Forehead / Temple Area:

- Intradermal injections 0.05ml.
- Volume total not to exceed 3ml for forehead.

Naso-labial folds/Upper Lip:

- Sub-dermal & intradermal injections
- Linear threading technique 0.2ml per injection.
- Volume total not to exceed 2-3 ml per side.

Chin / Periorbital Area:

- Linear threading technique 0.2ml per injection.
- Volume total not to exceed 2-3ml per side.

Upper eyelid / Lower eyelid area:

- Sub-dermal injections
- Punctate placement technique 0.2ml each x 1cn apart – massage evenly (separate skin from tissue)
- Volume total may not exceed 1-2ml per side.

Cheeks / Neck Area:

- Sub-dermal & intradermal injections at areas of concern.
- Avoid medial portion of neck (thyroid, hyoid bone) – stay lateral to structures
- Linear threading technique 0.2ml per injection.
- Volume total not to exceed 3-5ml per side.

Lips (Vermillion border)

- Linear threading technique 0.2ml per injection.
- Volume total not to exceed 0.4ml per quadrant.

PRP Rejuvenation Post-Procedure Instructions

WHAT TO EXPECT:

Day 1:

- Erythema and red appearance. Severity will depend upon how aggressive the treatment was performed and how your skin reacts.

Day 2:

- A reddish or pink hue and mild swelling may persist.

Days 3-7:

- Skin will feel rough like sandpaper lasting up to 5 days. Do not use any sort of scrub to speed up this process as it can cause moderate to severe skin irritation.

HOME CARE:

- Avoid direct sun exposure for 10 days if possible.
- Wash the face thoroughly a few hours after the treatment. Gently massage the face with tepid water and remove all serum and other debris (there may be some dried blood that you can remove at this
  time). You may use a very gentle cleanser avoiding any type with acids such as AHA and scrubs.
- Avoid the sun and do not apply sunscreen the same day as the treatment unless it is paraben free. Undesirable chemicals in most sunscreens can penetrate the skin causing irritation and possible breakouts.

For the first few days after treatment the skin will be very dry and tight, use of moisturizers or hydrators is optimal. The moisturizer or hydrator needs to be paraben free and will sooth the skin while speeding up the recovery process. Mineral makeup can be used beginning the day after your treatment.

After 2-3 days, you may resume your normal skin care routine. Vitamin A products are recommended, as well as peptides and growth factors. Avoid alcohol based toners for 10-14 days.

DEVELOPMENT & APPROVAL OF STANDARDIZED PROCEDURE

The Standardized Procedure and Protocol for the Administration of Microdermabrasion has been developed jointly by the Medical Director, Administrator, and the Registered Nurse. This protocol shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

_____ _____
Nurse Date

_____ _____
Medical Director Date

_____ _____
Administrator Date

PERSONNEL AUTHORIZED TO PERFORM PROCEDURE

NAME	DATE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____

MEDICAL GRADE CHEMICAL PEELS AND MICRODERMABRASION TREATMENTS

CLINICAL POLICIES AND PROCEDURES

SECTION 7

PURPOSE

To ensure safe and effective treatment of clients undergoing Medical Grade Chemical Peels and Microdermabrasion administration at the **[INSERT PRACTICE NAME]**, the following policies and procedures have been developed.

POLICY

A Registered Nurse [RN], Physician Assistant or licensed medical personnel with current state licensure shall be able to assess, consult and treat clients with Microdermabrasion following the guidelines set herein.

SETTING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel can perform the administration of Microdermabrasion in various settings and locations, such as but not limited to:

- Physician Office
- Satellite clinic / health care office(s)
- Medspa Setting authorized by the Medical Director
- Health Club Setting[8] authorized by the Medical Director

All Microdermabrasion procedures shall be performed in a clean, safe environment properly equipped with universal precautions in place.

SUPERVISION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary.

Adverse reactions such as bruising, swelling or infection shall be reported immediately to the Medical Director and shall be documented in the client's chart.

PATIENT CONDITIONS

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will not knowingly treat any clients with active herpes simplex blisters or cold sores.

[8] California Business & Professions Code Section 2725 and California Code of Regulations, Section 1470-1474; Health Club Setting does not meet California performance standards. May apply in other states.

PRECAUTIONS

Clients shall be advised of the following:

- Discontinue using certain topical agents [glycolic acids, alpha-hydroxy acids, Retin-A and Renova], for several days prior to microdermabrasion procedure.
- Remove contact lenses prior to treatment
- Certain facial skin disorders [acne, rosacea or telangiectasia] may be reason to not pursue treatment.
- If pronounced erythema [caused by sensitive skin] results, cease further treatments and seek re-evaluation from Medical Director.

Conditioning the skin prior to Microdermabrasion, is a critical factor in the overall outcome and resulting patient satisfaction [2 - 4 weeks is average]. The use of appropriate topical agents [except as noted above] can increase skin receptivity and responsiveness by reducing the stratum corneum barrier and by speeding up the skin's metabolism.

MICRODERMABRASION PROCEDURE

Microdermabrasion treatment(s) are administered in three phases.[9] Each phase of the procedure will be guided by the client's skin reaction.

- Phase One - consists of small, rapid sweeps. Brush off the crystals and evaluate work.

- Phase Two - includes the eraser-like linear sweep, the circular sweep and the square pattern sweep. Always wipe crystals from the skin after each phase.

- Phase Three - is optional. Some clients are too red to go on. Use this phase to blend the complexion, using the linear sweep to even out the tone.

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

1. Remove makeup, using a cleanser suitable for the skin type.

2. Degrease the skin [optional].

3. Thoroughly dry the skin with clean gauze.

4. Microdermabrasion procedure, as stated in Phase 1 and 2. Avoid areas of raised moles, warts, skin cancer, rosacea and exposed capillaries. Hyperpigmentation should be treated with high crystal volume; quick strokes and only low to moderate crystal velocity [to avoid overstimulation of melanocytes].

5. Rinse the skin with soothing lotion using gauze pads.

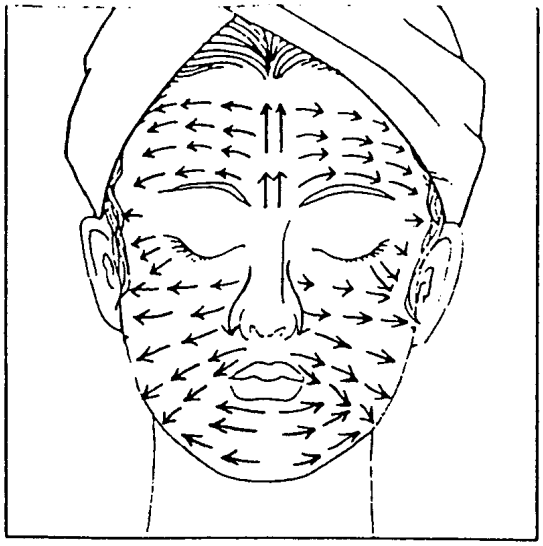
6. Apply a moisturizing cream with a light massage.

7. Apply a hydrating mask for a minimum of ten minutes.

8. Apply a soothing protective cream with SPF 30 or higher.

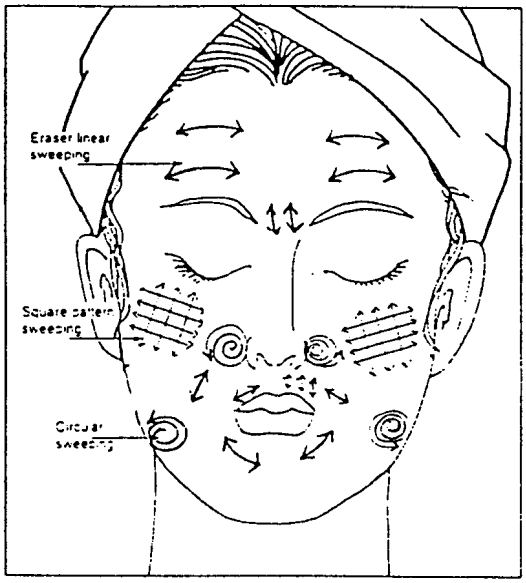
[9] Reference phase chart.

Phase-1 Linear Sweeping



Complete Phase-1 by sweeping powder off the skin with a soft facial brush. Reassess the depth of the treatment before going to Phase-2.

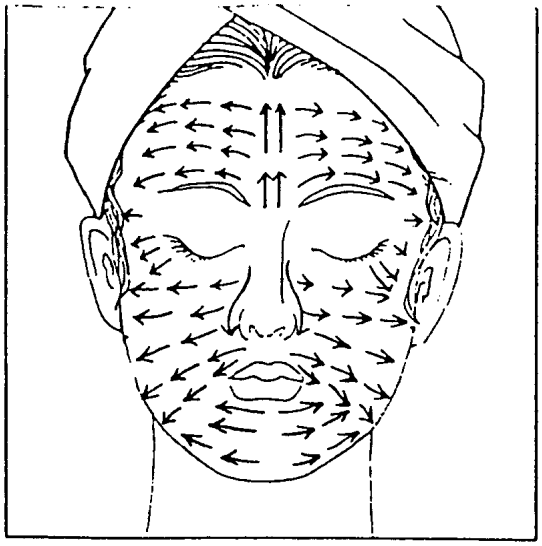
Phase-2



Phase-2 consists of: a) Eraser-like sweeping; b) Circular sweeping and c) Square pattern sweeping.

Phase-3 Optional

Remove all powder from the face between phases. Reassess the depth of the abrasion. Do not use Phase-3 if skin is red.



Alpha-Hydroxy (AHA) Medical Grade Peels

Information Statement

WHY a Micropeel and its process….

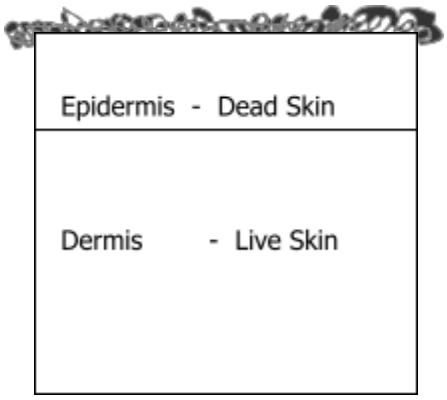
When you're young, the epidermis (dead tissue) is thin – Your dermis (live tissue) is thick… Your cells rotate every 28 days (cell turnover) keeping your skin rotating and lively… As we age they reverse… Your 'dead' tissue gets thicker and more compact while your 'live' tissue get thinner...

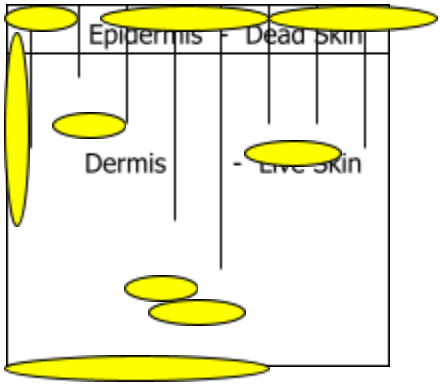
Why? Through life we encounter sun damage, smoker's environments, pollution, etc. known as 'free radicals'. Free radicals damage the collagens by attacking them and binding them up - essentially disabling them so that they are unable to promote cell turnover. When this occurs and your 'dead' tissue begins to thicken and compact – your cosmeceuticals and skincare can't penetrate through the epidermis to the live tissue, leading to premature aging, wrinkles, etc.

The skin is an environmental barrier designed to keep things out… unfortunately, it also keeps the bad things in (the free radicals)… at that current state –generally only about one tenth of one percent of the nutrients applied to the skin will make its way through to your live tissue…

Micro-peels are a process that enables us to penetrate the skin to allow antioxidants to affect the dermis (live tissue)… a **good** antioxidant - because of what it's made of… is a better food source for the free radicals – the free radicals will jump from the collagens to the anti-oxidant and then be flushed out of the body through the bloodstream. Causing the once stagnant collagens to once again promote the cell turnover in the dermis needed to maintain a younger, healthier and more vibrant skin appearance.

Alpha Hydroxy Acids, (AHA's) which are most commonly known as lactic and glycolic etc. is the first layer of chemical peeling agent applied to the skin. These 'acids' break the 'glue' or 'bonds' that hold the cells together. It helps remove a superficial layer of dead skin cells. We follow this with a microderm abrasion treatment (MDA) that will further eliminate major dead cells that are stopping product penetration. We then follow this step with an additional chemical peel at a stronger pH concentration which allows for us to create our 'windows of opportunity' into the dermis…





This is where true anti-aging or fighting acne begins with your patient. You have to affect **live** tissue. Just to perform a treatment that only consist of an MDA or exfoliation of the skin – WILL NOT ANTI-AGE your client. They only way to anti-age or affect overall skin condition and appearance for long lasting results is to generate cell turnover in the live tissue. This is only achieved truly – with a medical grade chemical acid with the pH below a 4. An aesthetician by law – working on her own, is not allowed to touch the dermis. The natural pH of the skin averages 4.5 – the only acids she can obtain are of a pH of 6 and above. Not allowing true penetration to the dermal layer. Medical grade acids are a pH of 3 and below.

The recommendation for achieving the best optimum result is to do a series of 6 treatments to 'kick' in the cell turnover at a faster rate. One treatment a week for three weeks and then every other week for an additional three treatments. If your skin rotates every 28 days… we are hitting it hard with micropeels every 7 days… this jumps start the skin as it is not able to keep up with the cell turnover we are forcing it to produce. We have also created a 'superficial' wound to the face - further making the skin produce 'healing' agents in the body to help produce the collagens at a faster rate than normal. The client should see exceptional results within the first month of their treatments.

MEDICAL GRADE CHEMICAL PEEL PROCEDURE

Protocol for AHA Acids 20% to 60%

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

- Complete assessment and a medical history questionnaire with all new clients. Record complete patient skin history. Any patient receiving or taking Retinoic acid treatments must be stopped (3-5) days prior to any acid peel procedure.

- Do not treat any patient who is being treated with Accutane, a period of (6) months must elapse before applying any acid to the skin.

- Upon passing medical screening, client will be fully informed of risks, benefits, and potential adverse reactions and an informed consent will be signed.

- Contraindications: Do not use this product on any person who is allergic to any ingredients in the formulation:
    - **Lactic acid** – do not use if the person has a true allergy to milk or milk products.
    - **Glycolic acid** – do not use if the person is allergic to strawberries or sugar.
    - **Salicylic acid** – do not use if the person has a severe sensitivity to aspirin.

- Secure patient's hair and cleanse area, patient is in a relaxed supine position and apply eye shield for the entire procedure.

- Thoroughly shake solution, measure 3ml and place in plastic cup, start timer to (7) minutes.

- Use appropriate peel technique using a brush, do not allow solution to drip and apply acid in single strokes across forehead and other facial areas in an orderly fashion methodically covering all areas.

- Observe treated area carefully. Note time of earliest erythema inpatient's chart. Elapsed time should not be greater than 7 minutes. At first sign of severe erythema or per patient request begin neutralizing acid solution. Erythema may not be uniform in presentation, but simple erythema on the cheek or elsewhere.

- Neutralize solution by applying 10% sodium bicarbonate with a saturated 4" x 4" cotton pad. Neutralize in the reverse order of application, starting with eyelids. Repeat rinse; if any areas continue to sting or if any slick or tacky surfaces are detected, rinse again.

- Apply test patch to test patch area (i.e. behind ears) by titrating the concentration of acid in 10% increments behind each ear. Neutralize test patch after (3) minutes by applying 10% sodium bicarbonate with a saturated 4" x 4" cotton pad.

- Apply Sun Block or appropriate topical moisturizer, Discuss the importance of maintaining the treatment results with the appropriate skincare maintenance products. The next appointment will be scheduled per treatment schedule accordingly.

- If patient is returning for additional treatment from the series of treatments prescribed prior you must evaluate the test patch from the prior visit. A positive test patch will have excessive erythema, pre-ulceration, ulceration, pigmentation changes to the skin or other denaturing qualities. If the presence of any of the preceding conditions have occurred, all treatments will be terminated and will be reported to the medical director or residing physician for further instruction. No other treatments may be applied without evaluation.

Note: If acid makes contact with eyes flush water for 15 minutes, occasionally lifting upper/lower lids, until no evidence of chemical remains. Continue flushing with normal saline until pH has returned to normal (30-60 minutes.) Get medical attention immediately. REFER TO MANUFACTURER PROTOCOLS FOR ADDITIONAL INSTRUCTION FOR ADMINISTRATION OF AHA MEDICAL GRADE PEELS

Sanitation and Health Safety Protocol

- All implements that come in contact with human skin and/or a mucus membrane should be sanitized in Bio-Tech or alcohol. This includes laser tips and microdermabrasion tips.
- All used microdermabrasion tips should be removed immediately with a gloved hand and placed in Bio-Tech or alcohol. A used tip should never remain on the hand piece.
- Should a microdermabrasion tip come in contact with an open lesion, blood, or any type of bodily fluid, the tip should be disposed of in a Bio-Hazard container as well and replaced immediately.
- All sanitized microdermabrasion tips should be handled and placed on the hand piece with a gloved hand.
- All persons giving a treatment should never come in contact with the recipient's skin and/or mucus membrane; gloves should be worn at ALL times.
- Gloves should be worn while handling all chemicals and acids, as repeated exposure can cause injury to the person performing the procedure.
- Any instruments used to puncture the skin should be placed in a sharps container immediately after use.
- Any disposable implements such as cotton tip swabs, gauze, cotton rounds, and tongue depressors, used during the procedure should be disposed of immediately after the procedure. If any of these implements come in contact with bodily fluids, they are to be disposed of in a Bio-Hazard container and/or bag.

MEDICAL GRADE CHEMICAL PEEL PROCEDURE

Protocol for BHA Acids 10% to 30%

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

- Complete assessment and a medical history questionnaire with all new clients. Record complete patient skin history. Any patient receiving or taking Retinoic acid treatments must be stopped (3-5) days prior to any acid peel procedure. Do not treat any patient who is being treated with Accutane, a period of (6) months must elapse before applying any acid to the skin. Pregnancy is contra-indicated.

- Upon passing medical screening, client will be fully informed of risks, benefits, and potential adverse reactions and an informed consent will be signed.

- Contraindications: Do not use this product on any person who is allergic to any ingredients in the formulation:
  Salicylic acid – do not use if the person has a severe sensitivity to aspirin.

- Secure patient's hair and cleanse area, patient is in a relaxed supine position and apply eye shield for the entire procedure.

- Thoroughly shake solution, measure 3ml and place in plastic cup, start timer to (7) minutes.

- Use appropriate peel technique using a brush, do not allow solution to drip and apply acid in single strokes across forehead and other facial areas in an orderly fashion methodically covering all areas.

- Observe treated area carefully. Note time of earliest erythema inpatient's chart. Elapsed time should not be greater than 7 minutes. At first sign of severe erythema or per patient request begin neutralizing acid solution. Erythema may not be uniform in presentation, but simple erythema on the cheek or elsewhere.

- Reapply acid to any area where white mask or frost is not showing.

- Remove frosting with a 4 x 4 saturated with Gentle Toner, Absorbic Acid or any gentle topical including cool water. Do not rub the skin.

Note: After four to five minutes frosting is completely formed. Patient discomfort is completely diminished. Patient may experience some tightness at this point and may be slightly anesthetized to a light touch for up to 30 minutes.

- Apply Moisturizer or Hydration Lotion to all treated areas. This product can be used up to least five to six times daily for the next seven to ten days to relieve any discomfort from peeling.

- Apply test patch to test patch area (i.e. behind ears) by titrating the concentration of acid in 10% increments behind each ear. Remove test patch frosting with a 4 x 4 saturated with Gentle Toner, Absorbic Acid or cool water.
- Apply Sun Block or appropriate topical moisturizer, Discuss the importance of maintaining the treatment results with the appropriate skincare maintenance products. The next appointment will be scheduled per treatment schedule accordingly.
- If patient is returning for additional treatment from the series of treatments prescribed prior you must evaluate the test patch from the prior visit. A positive test patch will have excessive erythema, pre-ulceration, ulceration, pigmentation changes to the skin or other denaturing qualities. If the presence of any of the preceding conditions have occurred, all treatments will be terminated and will be reported to the medical director or residing physician for further instruction. No other treatments may be applied without evaluation.

Note: If acid makes contact with eyes flush water for 15 minutes, occasionally lifting upper/lower lids, until no evidence of chemical remains. Continue flushing with normal saline until pH has returned to normal (30-60 minutes.) Get medical attention immediately. REFER TO MANUFACTURER PROTOCOLS FOR ADDITIONAL INSTRUCTION FOR ADMINISTRATION OF AHA MEDICAL GRADE PEELS

Sanitation and Health Safety Protocol

- All implements that come in contact with human skin and/or a mucus membrane should be sanitized in Bio-Tech or alcohol.
- Microdermabrasion is not recommended for use with BHA and/or Sal
- All persons giving a treatment should never come in contact with the recipient's skin and/or mucus membrane; gloves should be worn at ALL times.
- Gloves should be worn while handling all chemicals and acids, as repeated exposure can cause injury to the person performing the procedure.
- Any instruments used to puncture the skin should be placed in a sharps container immediately after use.
- Any disposable implements such as cotton tip swabs, gauze, cotton rounds, and tongue depressors, used during the procedure should be disposed of immediately after the procedure. If any of these implements come in contact with bodily fluids, they are to be disposed of in a Bio-Hazard container and/or bag.

MEDICAL GRADE CHEMICAL PEEL PROCEDURE

Protocol for Jessner's Acids
Modified, Lite, Ultra or Other

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

- Complete assessment and a medical history questionnaire with all new clients. Record complete patient skin history. Any patient receiving or taking Retinoic acid treatments must be stopped (3-5) days prior to any acid peel procedure. Do not treat any patient who is being treated with Accutane, a period of (6) months must elapse before applying any acid to the skin. Pregnancy is contra-indicated.

- Upon passing medical screening, client will be fully informed of risks, benefits, and potential adverse reactions and an informed consent will be signed.

- Contraindications: Do not use this product on any person who is allergic to any ingredients in the formulation:
    - **Lactic acid** – do not use if the person has a true allergy to milk or milk products.
    - **Glycolic acid** – do not use if the person is allergic to strawberries or sugar.
    - **Salicylic acid** – do not use if the person has a severe sensitivity to aspirin.
    -
- Secure patient's hair and cleanse area, patient is in a relaxed supine position and apply eye shield for the entire procedure.
    -
- Thoroughly shake solution, measure 3ml and place in plastic cup, start timer to (7) minutes.

- Use appropriate peel technique using a brush, do not allow solution to drip and apply acid in single strokes across forehead and other facial areas in an orderly fashion methodically covering all areas.

- Observe treated area carefully. Note time of earliest erythema inpatient's chart. Elapsed time should not be greater than 7 minutes. At first sign of severe erythema or per patient request begin neutralizing acid solution. Erythema may not be uniform in presentation, but simple erythema on the cheek or elsewhere.

- Allow solution to dry. Expect to see some white frosting as the solution dries. Apply successive layers and allow to dry to control the depth of the peel. Each layer should dry in two to four minutes.

- Peel will remain on skin; do not remove. No vitamins are applied at this time as any remaining acid on the skin will destroy any nutrients.

- Reapply acid to any area where white mask or frost is not showing.

- Skin frosting may be removed with a 4 x 4 saturated with cool water. Do not rub the skin.

Note: After four to five minutes frosting is completely formed. Patient discomfort is completely diminished. Patient may experience some tightness at this point and may be slightly anesthetized to a light touch for up to 30 minutes.

- Apply Moisturizer or Hydration Lotion to all treated areas. This product can be used up to least five to six times daily for the next seven to ten days to relieve any discomfort from peeling.

- Apply test patch to test patch area (i.e. behind ears) by titrating the concentration of acid behind each ear. Remove test patch frosting with a 4 x 4 saturated with cool water. This is only used when titrating the Jessner's solution for subsequent treatments.

- Apply Sun Block or appropriate topical moisturizer, Discuss the importance of maintaining the treatment results with the appropriate skincare maintenance products. The next appointment will be scheduled per treatment schedule accordingly.

- Jessner's Peels are for maintenance and not therapeutic. If patient is returning for additional treatment and you wish to titrate the formulation you must evaluate the test patch from the prior visit. A positive test patch will have excessive erythema, pre-ulceration, ulceration, pigmentation changes to the skin or other denaturing qualities. If the presence of any of the preceding conditions have occurred, all treatments will be terminated and will be reported to the medical director or residing physician for further instruction. No other treatments may be applied without evaluation.

Note: If acid makes contact with eyes flush water for 15 minutes, occasionally lifting upper/lower lids, until no evidence of chemical remains. Continue flushing with normal saline until pH has returned to normal (30-60 minutes.) Get medical attention immediately. REFER TO MANUFACTURER PROTOCOLS FOR ADDITIONAL INSTRUCTION FOR ADMINISTRATION OF AHA MEDICAL GRADE PEELS

Sanitation and Health Safety Protocol

- All implements that come in contact with human skin and/or a mucus membrane should be sanitized in Bio-Tech or alcohol.
- Microdermabrasion is not recommended for use with BHA and/or Sal
- All persons giving a treatment should never come in contact with the recipient's skin and/or mucus membrane; gloves should be worn at ALL times.
- Gloves should be worn while handling all chemicals and acids, as repeated exposure can cause injury to the person performing the procedure.
- Any instruments used to puncture the skin should be placed in a sharps container immediately after use.
- Any disposable implements such as cotton tip swabs, gauze, cotton rounds, and tongue depressors, used during the procedure should be disposed of immediately after the procedure. If any of these implements come in contact with bodily fluids, they are to be disposed of in a Bio-Hazard container and/or bag.

ACID PEEL BASICS

Absolute Contraindications

- All participants who have ever used Accutane… must have been off 12 months
- No use of Retin-A products for at least 48 hours – pre or post peel
- Lactic Acid – Allergies to milk (not necessarily lactose intolerant)
- Glycolic Acid – Allergies to strawberries (sugar)
- Salicylic Acid – Allergies to aspirin
- Jessner Acids – Milk or Aspirin
- Prone to Fever Blisters – should be on Zovarax or Acyclovir for 7 days prior
- No peels on pregnant women. Especially anything containing salicylic

GENERAL RULE OF THUMB FOR FITZPATRICKS 5-6 (SOME 4'S)

- NEVER GO OVER A 45% GLYCOLIC
- OR ABOVE A 10% SALICYLIC

AHA ACIDS - (can be left on the skin up to 7 minutes then you must neutralize)

AHA Acids work by breaking up the 'glue' between the cells… softening it. Think of chipping away the mortar between bricks…. It is a 'loosening' acid

Lactic - (can be left on the skin up to 7 minutes then you must neutralize)

- Most gentle of all the acids
- Can be used on any Fitzpatrick
- The ONLY one you want to use on Rosacea
- The place to start!
- Larger molecular size… very gentle
- VERY hydrating… making it the acid of choice for DRY skin

Glycolic - (can be left on the skin up to 7 minutes then you must neutralize)

- Molecular size is smaller – so a little stronger than Lactic
- A good stepping stone from Lactic
- Tend to be more DRYING then Lactic…
- Making it a better choice for your Normal/oily skin types

BHA ACIDS (self neutralizing)

BHA Acids work by 'denaturing' the protein in the cell… and kill the cell. They are self-neutralizing and will work until the reach a sebum (oil) pocket and neutralize themselves out. You can put up to four layers on and with each layer it will go deeper until it hit's a new sebum pocket. This peel is also used for adult acnes and non-inflammatory lesions associated with acne where the desire is to thin the upper epidermal layers of the skin.

Salicylic

- Great for Acne/Oily
- Only start here IF they client is REALLY OILY and Acne… otherwise, start with the Lactic or Glycolic (30%) and work them up to the salicylic.
- The 'frosting' you see on the skin is partial denaturing of the cell and partial crystallization of the salicylic.

Jessner

- Great stepping stone for all the acids when you want to be more aggressive or possibly 'peel'
- Has both acid actions making it more aggressive (breaking up 'glue' from the lactic and denatures the protein to kill the cell from the salicylic)
- Start with the Lite Jessner – then promote to Ultra Jessner and then the Full Jessner (see the pH scale)

Facial Peel Consent / Microdermabrasion (MicroPeel)

Facial peels (hereinafter “clinical procedures”) and microdermabrasion can provide marked improvement in the appearance of one’s skin for certain conditions. It is not, however, a “cure all” procedure. Therefore, it is very important that you have a thorough understanding of what these clinical procedures can and cannot do for your particular skin condition. In addition, it is imperative that you acknowledge the potential risks associated with clinical procedures.
Before subjecting yourself to any clinical procedures, read carefully the following statements. After you have read each statement, please initial each respective statement in the space that has been provided.

_____ The clinical procedure has been explained to me in detail by the physician and/or members of the physician’s staff.

_____ I understand that the clinical procedure is a skin rejuvenation treatment and that I may need several administrations of clinical procedures in order to receive my best results.

_____ I understand that for optimum results, a home treatment program is needed to enhance the results of clinical procedures.

Discomfort: This is usually minimal and of short duration.
Swelling: This is very unusual, but if it occurs it will be minimal and subsides in a few hours to a few days.
Reddening: A red discoloration may persist anywhere from a few days to several weeks.
Demarcation: Refers to the difference in color, texture or pigmentation that may occur at the junction between the treated and non-treated skin areas.
Existing Blemishes: Moles, blood vessels (telangiectasias), freckles and sunspots may become more obvious and darker since the superficial layers of dead skin have been removed.
Eye Injury: If chemicals get into the eye, scarring and vision disturbances may occur. Protective safety glasses should be worn while chemicals are being used during the clinical procedure.
Scarring: Is very unusual, but may occur.
Pigmentation: Although extremely rare, temporary and possibly permanent changes in the color of the skin may occur.
Milia: May occur, but will disappear quickly.
Infection: Is extremely unlikely, but may occur. An outbreak of Herpes may occur in affected individuals (ask your doctor about an antiviral medication if you are prone to cold sores).
Hair Growth: If the dermaplaning phase of the peel is administered, hair is expected to grow back blunt ended. New hair will not appear darker or denser. However, I do understand that any hormonal imbalance that may be present within my anatomical system can alter the normal hair growth pattern and cause a darker and denser restoration process.

General:

Any and all risks and complications can result in additional surgery, hospitalization, time off from work and expenses to you.

- Should one or more of the foregoing complications arise, please notify the office immediately.
- Early detection and treatment may minimize the extent of a complication and future problems.
- The foregoing list is not intended to be a complete or exhaustive list of all possible complications which may arise as a result of clinical procedures.
- The physician will be glad to detail less likely complications or problems.

_____ I understand that clinical procedures need not be administered by a physician. It is also my understanding that, in addition to receiving formal training, any non-physician medical assistants (i.e., RN, LPN, physician assistant, ARNP, cosmetologist or aesthetician) who administers clinical procedures has had his/her skills reviewed and endorsed by the supervising physician.
_____ I understand that is extremely important to strictly follow all homecare instructions when striving for optimal results.
_____ I understand that if I experience any adverse side effects that appear to be attributable to my use of homecare products, I would discontinue use of the products immediately and notify the office.

I certify that I have read and understand ALL of the above. I have also been offered an opportunity to discuss same with a physician.

_____ _____
Patient Signature Date

_____ _____
Witness Date

MICRODERMABRASION CONSENT FOR TREATMENT

CLIENT NAME_____ DATE_____

MICRODERMABRASION is a procedure that works by removing a portion of the epidermis using a combination of controlled suction concomitantly with air abrasion utilizing aluminum oxide particles. To achieve desired effects and visible improvements, multiple treatments may be required.

THE FOLLOWING HAVE BEEN DISCUSSED WITH ME:

Potential Benefits of the proposed procedure, possible Alternative Medical Procedure (s), Complications/Risks, Healing Period; including but not limited to temporary tightness which generally resolve with 4-24 hours after the procedure. If aggressive treatment of acne scars are performed, then additional aftercare management may be utilized.

I AM AWARE OF THE FOLLOWING POSSIBLE RISKS WITH MICRODERMABRASION:

DISCOMFORT – If discomfort is experienced, immediately inform the nurse.

WOUND HEALING – Generally not applicable [open wounds should not exists]. Aggressive treatment(s) [acne scar] may cause crusting and inflammation.

BRUISING/SWELLING/INFECTION – Bruising and swelling generally do not occur. Skin infection is a possibility any time a skin procedure is performed. However in this procedure the epidermis has only been partially removed so the possibility is highly unlikely.

PIGMENT CHANGES [Skin Color] – Microdermabrasion is the removal of the stratum corneum [the uppermost level of the epidermis] and pigment changes are unlikely. However, as with any abrasive [depending on the depth within skin] there is always a risk.

SCARRING – Scarring is a rare occurrence, but possible, when the skin's surface is disrupted. To minimize the chances of scarring, all post-operative instructions must be carefully followed.

EYE EXPOSURE – Protective eyewear will be provided. It is important to keep those eyewear on at all times during the treatment in order to protect your eyes from accidental particle exposure.

LINES/STREAKING – Although uncommon, temporary lines or streaking of the skin may occur, which may last for several days.

HERPES SIMPLEX BLISTERS/COLD SORES – If you have a history of herpes simplex or cold sores, a reactivation of this condition can occur over the treated area.

ACKNOWLEDGEMENT:

By my signature below, I certify that I have read and fully understand the contents of this permission form, have no contraindicating factors, and thereby grant permission for microdermabrasion treatment.

_____

Client [Print Name] Signature Date

_____

Witness [Print Name] Signature Date

MICRODERMABRASION POST TREATMENT INSTRUCTIONS

- Avoid swimming in a chlorinated pool the day of the procedure.
- Avoid tanning beds for at least one week after the treatment.
- Waxing of the treated areas should be avoided for two weeks post-procedure.
- Topical preparations can significantly enhance the skin's recovery and decrease inflammation. Client's skin will feel like a slight wind or sun burn. Avoid retinoic acids and glycolic acids for three weeks.
- Maintain hydration [both topically and internally] by drinking plenty of water.
- Moisturizers and sunscreen should be applied before leaving the treatment room. Use a strong moisturizer along with sun block SPF30 or more. Moisturize and reapply sunscreen several times during the day, as needed, and to avoid direct sunlight.

Treatments can be repeated every two weeks. Maintenance treatments can be scheduled between four to five weeks to maintain the level of rejuvenation the skin has developed. It takes 48-hours to rebuild hyper-lipids in epidermis.

RECORD KEEPING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall be responsible for maintaining client records, including but not limited to client assessment, signed informed consent of risks, benefits, and potential adverse effects, number of treatments, and the client response to treatment including the quality of skin, pigmentation changes, and elasticity.

REQUIREMENTS FOR REGISTERED NURSE

TRAINING / EDUCATION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall receive specialized training [and be certified] in the administration of Microdermabrasion. A Medical Doctor, Doctor of Osteopath, Advanced Registered Nurse Practitioner experienced in this procedure, or a teaching institution specializing in this procedure, may perform this training and certification. Competencies to successfully demonstrate shall include:

- Mechanism of Action of Microdermabrasion
- Basic Theory of Treatment for Cosmetic Purposes
- Facial Anatomy
- Indications for use
- Contraindications for use
- Skin precautions
- Preparation of the skin
- Safety, efficacy, and complication issues
- Assessment and identification of areas to be treated
- Safe application of Microdermabrasion technique [minimum 4-hours hands on training]

NOTE: If Microdermabrasion is used as a cosmetic treatment [i.e. only affects the outermost layer of the skin or the stratum corneum] then a licensed cosmetician or esthetician may perform the treatment. However, if it is administered as a medical treatment [i.e. procedure penetrates to deeper levels of the epidermis or in conjunction with a medical peel] then it must be performed by a physician, physician assistant, advanced practice nurse and registered nurse under supervision. Treatments to remove scarring, blemishes, or wrinkles are considered a medical treatment. Unlicensed personnel, including medical assistants may not perform any type of microdermabrasion.[10]

[10] California Business & Professions Code, Section(s) 2069-2071 and Title 16 California Code of Regulations, Section(s) 1366-1366.4.

COMPETENCIES and DOCUMENTATION

The Medical Director and/or [applicable licensure], shall

- Document [on the appropriate form] the initial evaluation and final determination recording satisfactory completion of training and competence.

- Evaluate the competence of the Registered Nurse [RN], Physician Assistant or licensed medical personnel on an annual basis and/or as needed if indicated by client dissatisfaction or efficacy issues.

- The evaluation shall be maintained in the personnel file of the Registered Nurse [RN], Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].

Reference: Use of Lasers, Dermabrators, Botox and Other Treatments by Non-Physicians, Medical Board of California Action Report, page 6, October 2012.

DEVELOPMENT & APPROVAL OF STANDARDIZED PROCEDURE

The Standardized Procedure and Protocol for the Administration of Microdermabrasion has been developed jointly by the Medical Director, Administrator, and the Registered Nurse. This protocol shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

_____ _____
Nurse Date

_____ _____
Medical Director Date

_____ _____
Administrator Date

PERSONNEL AUTHORIZED TO PERFORM PROCEDURE

NAME	DATE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____

MICRONEEDLING & SCAR REVISION TREATMENTS

CLINICAL POLICIES AND PROCEDURES

SECTION 8

PURPOSE

To ensure safe and effective treatment of clients undergoing micro-needling or dermal roller treatments and administration at the [**INSERT PRACTICE NAME**], the following policies and procedures have been developed.

POLICY

A Registered Nurse [RN], Physician Assistant or licensed medical personnel with current state licensure shall be able to assess, consult and treat clients with micro-needling, dermal roller revision to the skin following the guidelines set herein.

SETTING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel can perform the administration of Laser Hair Removal in various settings and locations, such as but not limited to:

- Physician Office
- Satellite clinic / health care office(s)
- Medspa Setting authorized by the Medical Director
- Health Club Setting[11] authorized by the Medical Director

All micro needling procedures shall be performed in a clean, safe environment properly equipped with universal precautions in place.

SUPERVISION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary.

All adverse reactions such as epidermal injury, pain, erythema, edema, blistering, dyschromia [hyper or hypopigmentation] textural changes [crusting or scabbing] and/or bruising shall be reported immediately to the Medical Director. Side effects may appear either at the time of treatment or shortly thereafter. Adverse reaction(s) shall be documented in the client's chart.

[11] California Business & Professions Code Section 2725 and California Code of Regulations, Section 1470-1474; Health Club Setting does not meet California performance standards. May apply in other states.

PATIENT CONDITIONS

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will not knowingly treat clients' with / on / using:

- The herpes simplex virus. In an effort to prevent a "flair up" of a client(s) condition, treatment to the upper lip, chin, lower cheeks or bikini line should be avoided. The risk of complication(s) may be reduced if prescribed antiviral medication [i.e. Zovirax or Famvir] are taken for several days prior to and after each treatment.

- A tan from sun exposure, tanning booth, self -tanning preparations. Client(s) who have a tan shall be instructed to stay out of the sun and return for treatment when the tan is gone.

- Atypical moles or malignancy, pigmented lesions, tattoos [including permanent cosmetic tattoos], or vascular lesions in the treated area.

- Isotretinoin [commonly referred by the trade name Accutane®] within 6-12 months.

- Pregnancy or breast feeding.

- History of keloid scarring or hypertrophic scarring.

- Insulin-dependent Diabetes or other medical at risk conditions.

- Scarring or infection at treatment site.

TREATMENT CONSIDERATIONS

- A warm flushing of the skin may occur immediately after the procedure as blood will rush to the injection sites.

- Aestheticians may administer this procedure to a needle depth of .3mm, any longer needle lengths must be administered by a healthcare professional licensed to break the skin and administer these types of injections as per recent FDA Guidance rulings and recommendations.

- The first two treatments should be (2) to (4) weeks apart. The third treatment will be optional based upon the client's evaluation [correction of the condition treated].

SAFETY PROCEDURES

A well-trained staff primarily assures patient safety. In an effort to protect both the operator and client, the following safety measures[12] shall be observed:

- Corneal shields shall be placed on client's eyes prior to the procedure if micro-needling is considered for the facial areas.

- Protective eyewear shall be available at all entrances to treatment room(s).

- Topical anesthesia may be administered prior to the procedure, please review anesthesia protocols for use. All topical solutions other than what will be used in the procedure will need to be removed from patients' skin before beginning the procedure.

[12] OSHA [Occupational Safety & Health Administration] Publication 8-1.7 Guidelines for Laser Safety and Hazard Assessment.

MICRO NEEDLING PROCEDURE

Protocol for Needle Dermal Roller or Other Micro Needling Device

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

- Complete assessment and a medical history questionnaire with all new clients. Record complete patient skin history. Any patient receiving or taking Retinoic acid treatments must be stopped (3-5) days prior to the procedure. Do not treat any patient who is being treated with Accutane, a period of (6) months must elapse before applying any acid to the skin. Pregnancy is contra-indicated.

- Upon passing medical screening, client will be fully informed of risks, benefits, and potential adverse reactions and an informed consent will be signed.

- Secure patient's hair and cleanse area, patient is in a relaxed supine position and apply eye shield for facial rejuvenation procedures for the entire procedure.

- Remove from patient's skin any topical solutions or makeup, apply topical anesthesia to the appropriate areas of the skin for treatment. Only larger needle depth treatments (>.5mm) require anesthesia, please see table 1.0 for needle sizing chart and appropriate areas of treatment.

- Use appropriate amount of topical anesthesia (BLT Formulation – 8/12/8), wait until face is anesthetized (typically 5-10 minutes) and remove the formulation from the skin with alcohol or witch hazel.

- Apply topical solution to the prospective treated area; suitable topical solutions may include platelet rich plasma from patient, platelet poor aspirate from patient, un-crosslinked HA, sterile glycol based topicals, DMAE and Absorbic Acid topical, or any other topical as instructed by the physician.
-
- **Dermal rollers** are <u>only</u> indicated for behind the thighs for cellulite or for dimpling of the buttocks area. Dermal rollers may also be used for acne scarring or skin pleating of the cheeks only and is by the direction of the physician. Dermal rollers are for single patient use only and must be discarded after treatment into the appropriate biohazard sharps container.

- The [enter product name] skin needling system (aka needle pen) is indicated for all body part areas and conditions in Table 1.0 but may not be as effective for treatment as compared to (7) indicated uses for dermal rollers. The physician or other supervising medical professional will prescribe which system to use.

- The protocol for cellulite of the thighs and dimpling of the buttocks using a dermal rollers will be (7) passes or more of the device over the treated area quickly as patient's will find comfort if the procedure is done in a timely manner. Additional

passes of the device (> 7) may be considered and will be based upon patient discomfort levels. Cross hatching of the direction of the strokes and speed of the strokes are encouraged for better results. Please see Table 1.0 for sizing chart for dermal roller size.

- The protocol for acne of the mid-face area (cheeks) using a dermal rollers will be (4) passes or more of the device over the treated area quickly as patient's will find comfort if the procedure is done in a timely manner. Additional passes of the device (> 4) may be considered and will be based upon patient discomfort levels. Again, cross hatching of the direction of the strokes and speed of the strokes are encouraged for better results. Please see Table 1.0 for sizing chart for dermal roller size.

- If using the [enter product name] skin needling system (aka needle pen) the protocol will be (4) passes or more of the device over the treated using a circular pattern. The device should be resting on the skin and no pressure given other than allowing the head of the device to gently glide over the skin in a circular motion. Additional passes of the device (> 4) may be considered and will be based upon patient discomfort levels. The needle heads of the device will be discarded after treatment into the appropriate biohazard sharps container. Changing of the needle heads is encouraged when treating larger body areas or large areas of the face. Do not exceed specifications set forth in Table 1.0.

- **Note:** Patient may experience pin point bleeding if using larger needle heads or dermal rollers, erythema and uncomfortable some tightness at this point and may be slightly anesthetized to a light touch for up to 30 minutes.

- Apply Moisturizer or Hydration Lotion to all treated areas. This product can be used up to least five to six times daily for the next seven to ten days to relieve any discomfort from peeling.

- Apply Sun Block or appropriate topical moisturizer, Discuss the importance of maintaining the treatment results with the appropriate skincare maintenance products. The next appointment will be scheduled per treatment schedule accordingly.

- If patient is returning for additional treatment from the series of treatments prescribed you must evaluate the patient from the prior visit, follow-up visits are scheduled at (2) to (4) week intervals. Access the indications for delayed healing, ulceration or hypertrophic scarring conditions to the area treated. If the presence of any of the preceding conditions have occurred, all treatments will be terminated and will be reported to the medical director or residing physician for further instruction. No other treatments may be applied without evaluation.

Sanitation and Health Safety Protocol

• All implements that come in contact with human skin and/or a mucus membrane should be sanitized in Bio-Tech or alcohol.
• Microdermabrasion is not recommended for use with BHA and/or Sal
• All persons giving a treatment should never come in contact with the recipient's skin and/or mucus membrane; gloves should be worn at ALL times.
• Gloves should be worn while handling all chemicals and acids, as repeated exposure can cause injury to the person performing the procedure.
• Any instruments used to puncture the skin should be placed in a sharps container immediately after use.
• Any disposable implements such as cotton tip swabs, gauze, cotton rounds, and tongue depressors, used during the procedure should be disposed of immediately after the procedure. If any of these implements come in contact with bodily fluids, they are to be disposed of in a Bio-Hazard container and/or bag.

Table 1: **Dermal Needle Roller/Dermal Needle Pen (Size/Indication Chart)**

Indication/Size	.20mm	.25mm	.50mm	.75mm	1.0mm	1.5mm	2.0mm	2.5mm
Hair Regeneration	X	X	X					
Fine Lines		X	X					
Anti-Aging /Wrinkles			X	X	X			
Pores/Pigmentation			X	X	X			
Acne Scars			X	X	X			
Superficial Scars			X	X	X			
Cellulite Indications					X	X	X	
Stretch Marks					X	X	X	X
Deep Scarring						X	X	X

Table 2: **Dermal Needle Pen (Depth Size/Speed of Device)**

- Depth < 0.50mm Speed 1-2
- Depth 0.50mm-0.75mm Speed 2-3
- Depth 0.75mm – 1.25mm Speed 3-4
- Depth 1.25mm – 1.50mm Speed 5-6
- Depth 1.50mm – 2.50mm Speed 6-7

Micro-Needling Post Procedure

Immediately after your Micro-Needling procedure, do not take any anti-inflammatory medications such as Ibuprofen, Motrin or Advil. These agents will interfere with the natural inflammatory process that is critical and responsible for your skin rejuvenation. Follow these simple steps:

Day of procedure: No lotions, makeup or other topical products on your face before your procedure. After your procedure your medical provider may apply a lipo-peptide booster, skin moisturizer, and sun screen. You may clean your face with a gentle cleanser before bed.

Day 1: On the next day, you may clean your face as usual and apply makeup, lotions and other topical products as usual. Stay away from exfoliants or glycolic acids that are present is cleaners as these can make your skin very dry after the procedure. Be sure to use an approved SPF30 or greater sunscreen!

Days 2-7: Within two (2) days following your Micro-Needling procedure, you will notice skin dryness and flaking. This is due to an increased turnover of skin cells. During this period, you may apply your regular skin moisturizer. Follow the instructions given to you by your medical professional. If your medical professional used the roller or needle device around the eyes, you may have a little micro bruising that may exist for three or four days. This can easily be covered with makeup.

Days later, your skin will start shedding. These are skin layers that would regularly shed a week later, but the Micro-Needling brings this skin to the surface sooner. During this temporary process, your skin will shed and be dry.

Days 7+: A week after the Micro-Needling procedure, most patients notice that their skin is smoother and more radiant.

Results vary, but usually a course of 1-3 treatments (maximum of 5, depending on the condition being treated) is typically recommended. If you require MORE procedures than this, you may have an unrecognized underlying medical condition and should consult with your provider. Of course, results may vary from patient to patient. Keep in mind that the healthier your body is, the better will be the results you achieve from a Micro-Needling procedure. Your body's function and overall health are reflected in your skin.

Micro Needling
Patient Consent Form

Description of the Procedure:
The [enter product name] skin needling system or dermal roller treatment allows for controlled induction of the skin's self-repair mechanism by creating micro "injuries" in the skin which triggers new collagen synthesis. The result is smoother, firmer and younger looking skin.

Skin needling procedures are performed in a safe and precise manner with the use of the sterile [enter product name] skin needling system or dermal roller treatment. The procedure is normally completed within 30-60 minutes depending on the required treatment and anatomical site.

Side Effects:
After the procedure, the skin will be red and flushed in appearance in a similar way to moderate sunburn. You may also experience skin tightness and mild sensitivity to touch on the area being treated. The skin's redness will diminish greatly after a few hours following the treatment and within the next 24 hours the skin will be generally calmed. After 3 days the skin will return to a normal or near normal appearance.

Contraindications:
Keloid scars; history of eczema, psoriasis and other chronic conditions; history of actinic (solar) keratosis; history of Herpes Simplex infections; history of diabetes; presence of raised moles, warts on targeted area. Other medical at risk conditions based upon your medical history may also contraindicate yourself from receiving treatment.

Absolute contraindications include; scleroderma, collagen vascular diseases or cardiac abnormalities; blood clotting problems; active bacterial or fungal infection; immuno-suppression; scars less than 6 months old. Not recommended for women who are pregnant or nursing.

Patient Consent:
I understand that results will vary between individuals. I understand that although I may see a change after my first treatment; I may require a series of sessions to obtain my desired outcome.

The procedure and side effects have been explained to me including alternative methods; as have the advantages and disadvantages. I am advised that though good results are expected, the possibility and nature of complications cannot be accurately anticipated and that, therefore, there can be no guarantee as expressed or implied either as to the success or other result of the treatment.

I am aware that the [enter product name] skin needling system or dermal roller treatment is not permanent as natural degradation will occur over time. I state that I have read (or it has been read to me) and I understand this consent and I understand the information contained in it.

I have had the opportunity to ask any questions about the treatment including risks or alternatives and acknowledge that all my questions about the procedure have been answered in a satisfactory manner.

THIS CONSENT FORM IS VALID UNTIL ALL OR PART IS REVOKED BY ME IN WRITING.

Print Name _____

Signature _____

Date _____

RECORD KEEPING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall be responsible for maintaining client records, including but not limited to client assessment, signed informed consent of risks, benefits, and potential adverse effects, number of treatments, and the client response to treatment including the quality of skin, pigmentation changes.

REQUIREMENTS FOR REGISTERED NURSE

TRAINING / EDUCATION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall receive specialized training [and be certified] in the administration of micro needling and the various devices (i.e. needle pen and needle rollers). A Medical Doctor, Doctor of Osteopath, Advanced Registered Nurse Practitioner experienced in this procedure, or a teaching institution specializing in this procedure, may perform this training and certification. Competencies to successfully demonstrate shall include:

- Mechanism of Action and indications for use.
- Preparation of the skin
- Safety, efficacy, and complication issues
- Assessment and identification of areas to be treated
- Safe application of micro needling techniques of various facial and body areas [minimum 8-hours hands on training]

NOTE: Micro needling to a depth of 0.3mm or greater may only be performed by a physician, physician assistant and/or registered nurse[13]. Unlicensed personnel, including medical assistants may not perform any type of micro needling greater than a 0.3mm depth.

[13] Sections 7312, Business & Professional Code. Reference: Sections 7312(e), 7316, 7320, 7320.1, Business and Professions Code.

COMPETENCIES and DOCUMENTATION

The Medical Director and/or [applicable licensure], shall

- Document [on the appropriate form] the initial evaluation and final determination recording satisfactory completion of training and competence.

- Evaluate the competence of the Registered Nurse [RN], Physician Assistant or licensed medical personnel on an annual basis and/or as needed if indicated by client dissatisfaction or efficacy issues.

- The evaluation shall be maintained in the personnel file of the Registered Nurse [RN], Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].

DEVELOPMENT & APPROVAL OF STANDARDIZED PROCEDURE

The Standardized Procedure and Protocol for the Administration of micro needling and scar revision including the treatment of cellulite (Grade III) has been developed jointly by the Medical Director, Administrator, and the Registered Nurse. This protocol shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

_____ _____
Nurse Date

_____ _____
Medical Director Date

_____ _____
Administrator Date

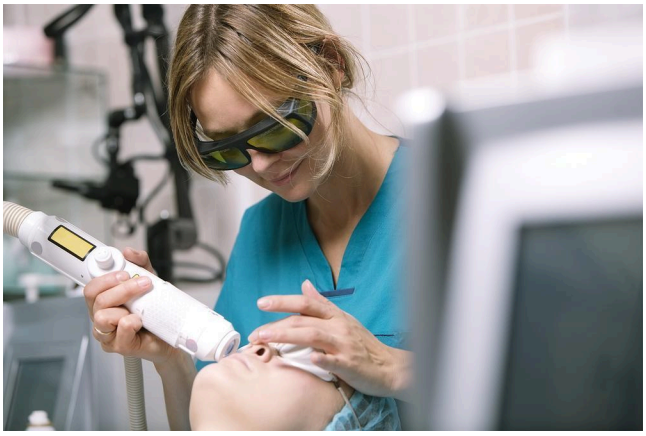
PERSONNEL AUTHORIZED TO PERFORM PROCEDURE

NAME	DATE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____

COSMETIC “NON-ABLATIVE” LASER LIGHT ENERGY TREATMENTS

GENERAL CLINICAL POLICIES AND PROCEDURES

- Laser or IPL Hair Removal (Reduction) Applications
- IPL (Photofacial) Applications
- Other Laser Applications (Other Indications for Use)



SECTION 9

PURPOSE

To ensure safe and effective treatment of clients undergoing Laser Hair Removal administration at the [**INSERT PRACTICE NAME**], the following policies and procedures have been developed.

POLICY

A Registered Nurse [RN], Physician Assistant or licensed medical personnel with current state licensure shall be able to assess, consult and treat clients with Laser Hair Removal following the guidelines set herein.

SETTING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel can perform the administration of Laser Hair Removal in various settings and locations, such as but not limited to:

- Physician Office
- Satellite clinic / health care office(s)
- Medspa Setting authorized by the Medical Director
- Health Club Setting[14] authorized by the Medical Director

All Laser Hair Removal procedures shall be performed in a clean, safe environment properly equipped with universal precautions in place.

SUPERVISION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary.

All adverse reactions such as epidermal injury, pain, erythema, edema, blistering, dyschromia [hyper or hypopigmentation] textural changes [crusting or scabbing] and/or bruising shall be reported immediately to the Medical Director. Side effects may appear either at the time of treatment or shortly thereafter. Adverse reaction(s) shall be documented in the client's chart.

[14] California Business & Professions Code Section 2725 and California Code of Regulations, Section 1470-1474; Health Club Setting does not meet California performance standards. May apply in other states.

PATIENT CONDITIONS

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will not knowingly treat clients' with / on / using:

- The herpes simplex virus. In an effort to prevent a "flair up" of a client(s) condition, treatment to the upper lip, chin, lower cheeks or bikini line should be avoided. The risk of complication(s) may be reduced if prescribed antiviral medication [i.e. Zovirax or Famvir] are taken for several days prior to and after each treatment.

- A tan from sun exposure, tanning booth, self -tanning preparations. Client(s) who have a sunburn or tan shall be instructed to stay out of the sun and return after resolution.

- Atypical moles or malignancy, pigmented lesions, tattoos [including permanent cosmetic tattoos], or vascular lesions in the treated area.

- Isotrentinoin [commonly referred by the trade name Accutane®] within 6-12 months.

- Photosensitive medications [i.e. Retin A, Alpha Hydroxyl or Glycolic Acid].

- Pregnancy or breast feeding.

- History of keloid scarring or hypertrophic scarring.

- Insulin-dependent Diabetes or any other "medical at risk" condition.

- Pacemaker or internal defibrillator

- Hirsutism[15] or PCOS from endocrine problems or medication induced hirsutism.

TREATMENT CONSIDERATIONS

- It may take up to two weeks for hair to fall out.

- Light hair may require more treatments than dark hair.

- The first two treatments should be four to six weeks apart. The third treatment will be optional based upon the client's evaluation [when hair re-growth starts to reappear].

[15] Hirsutism – excess growth of hair of normal or abnormal distribution.

LASER HAIR REMOVAL PROCEDURE

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

1. Complete / update the client's medical / physical history.

2. Exclude those having contraindications for treatment.

3. Determine the client's expectations and reason(s) for seeking treatment. Advise client about treatment arrangement, typical results, and possible adverse effects and discomfort.

4. Instruct client to shave area prior to procedure. Depilatory creams can be used with client(s) who object to shaving.

Warning: Long hair absorbs optical energy preventing delivery to the follicle and may damage the skin during the treatment. If the external hair shaft is present the laser will burn it, in turn burning the skin. Also, when treating certain areas [i.e. between eyebrows] the thermal effect may cause unintended areas to be affected.

5. Remove all make-up, lotion, perfume, deodorant, and sunscreen.

6. Instruct client about laser safety precautions [refer to Safety Procedures].

7. Prepare small area in treatment zone for test spots by applying thin layer of clear conductive gel. Test area that represents the general treatment zone in skin color and skin thickness.

8. Test optical fluences within appropriate range for the skin type [reference guidelines Laser Hair Removal Parameters]. Wait five to ten minutes for skin to react. Tanned or dark skin may take longer.

9. Treat with the highest tested optical fluence that does not leave prolonged diffuse epidermal erythema. Some perifollicular erythema/edema is acceptable. Diffuse epidermal pinkness should subside within 5-10 minutes. For areas of high density dark coarse hairs [i.e. men's beard area], start by using lower fluences then increase to higher fluences in future treatments as hairs become reduced and miniaturized.

10. Hair color and skin color determine the best fluence to use. Darker skin types IV to VI can be treated between 10 and 20 J/cm2. Fair skin types I to III can take the highest fluences, from 25 to 40 J/cm2.

Note: Each skin type has its own threshold fluence at which pigmentation changes occur. To minimize hypo or hyperpigmentation, lower fluences should be used. Single pulsing is recommended, double and triple pulsing can increase the incidence of pigment changes. If hypo or hyperpigmentation occurs it is usually transient.

11. Hydrate the treatment site with conductive gel. Ensure the skin is wet prior to pulsing.

12. Place the hand-piece perpendicular to the skin and apply gentle pressure. There should be slight compression and firm contact with the skin. Several pulses should then be placed next to one another while looking for the epidermal response. An effective fluence is one where the hair carbonizes, followed by selective follicular swelling and redness. Perifollicular swelling and redness are desired clinical endpoints. They indicate that the client has been treated with an appropriate fluence.

Note: It is important to regularly clean the hand-piece. When the hair shaft carbonizes, it leaves debris on the laser window. This build-up can make the hand-piece hot and make it difficult for the laser light to penetrate. Cleaning the hand-piece with alcohol prevents this barrier from forming. Between clients, the hand-piece should be disinfected with a liquid disinfectant such as Virex in order to prevent infection.

13. Remove gel from client's treated area. Use cool water or damp cloth to rinse any gel residue. If any epidermal effect develops, apply cool packs. Ice will provide relief and reduce the swelling duration.

14. Always apply sunscreen to face/neck or other exposed treatment area(s) if client will be outside during daylight hours. A topical cortisone cream may also be used. If there are signs of epidermal damage, the client should use an antibiotic ointment.

Note: Client should return within 4-8 weeks after treatment for evaluation of the treated anatomical site; one or two months for the face, armpit and bikini line.
On other sites [i.e., back and legs] the growth delay is usually two to three months.

If no clearance is observed, and there are no visible or noted adverse reactions to the first treatment, update client history [mindful of sun tanning or new medications]. Another treatment will be recommended if the client has not violated the contraindications.

Note: Some client(s) may benefit from the application of topical anesthetics prior to procedure.

SAFETY PROCEDURES

A well-trained staff primarily assures patient safety. In an effort to protect both the operator and client, the following safety measures[16] shall be observed:

- Corneal shields shall be placed on client's eyes prior to the procedure.

- Protective eyewear shall be available at all entrances to treatment room(s). Anyone wishing to enter a treatment room during a procedure shall knock appropriately and don protective eyewear prior to opening the door.

- Personnel shall at all times [while a laser procedure is in progress] ensure that everyone present in a laser-room has protective eyewear in place.

- Treatment room(s) shall be clearly marked with appropriate signs indicating the use of lasers.

- All windows shall be covered. Never permit reflective objects such as jewelry, watches, surgical instruments or mirrors to intercept the laser.

- Wet towels shall be kept in the treatment room in case of a fire.

RECORD KEEPING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall be responsible for maintaining client records, including but not limited to client assessment, signed informed consent of risks, benefits, and potential adverse effects, number of treatments, and the client response to treatment including the quality of skin, pigmentation changes.

[16] OSHA [Occupational Safety & Health Administration] Publication 8-1.7 Guidelines for Laser Safety and Hazard Assessment.

REQUIREMENTS FOR REGISTERED NURSE

TRAINING / EDUCATION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall receive specialized training [and be certified] in the administration of Laser Hair Removal. A Medical Doctor, Doctor of Osteopath, Advanced Registered Nurse Practitioner experienced in this procedure, or a teaching institution specializing in this procedure, may perform this training and certification. Competencies to successfully demonstrate shall include:

- Mechanism of Action of Laser Hair Removal
- Preparation of the skin
- Safety, efficacy, and complication issues
- Assessment and identification of areas to be treated
- Safe application of Laser Hair Removal technique [minimum 8-hours hands on training]

NOTE: Laser Hair Removal may only be performed by a physician, physician assistant and/or registered nurse[17]. Unlicensed personnel, including medical assistants may not perform any type of Laser Hair Removal.[18]

[17] Business & Professions Code, Section 2725(b)(4), (c) provides the statutory authority for registered nurses to perform medical functions pursuant to standardized procedures.

[18] California Business & Professions Code, Section(s) 2069-2071 and Title 16 California Code of Regulations, Section(s) 1366-1366.4.
Use of Lasers, Dermabrators, Botox and Other Treatments by Non-Physicians, Medical Board of California Action Report, page 6, October 2002.

COMPETENCIES and DOCUMENTATION

The Medical Director and/or [applicable licensure], shall

- Document [on the appropriate form] the initial evaluation and final determination recording satisfactory completion of training and competence.

- Evaluate the competence of the Registered Nurse [RN], Physician Assistant or licensed medical personnel on an annual basis and/or as needed if indicated by client dissatisfaction or efficacy issues.

- The evaluation shall be maintained in the personnel file of the Registered Nurse [RN], Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].

DEVELOPMENT & APPROVAL OF STANDARDIZED PROCEDURE

The Standardized Procedure and Protocol for the Administration of Laser Hair Removal has been developed jointly by the Medical Director, Administrator, and the Registered Nurse. This protocol shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

_____ _____
Nurse Date

_____ _____
Medical Director Date

_____ _____
Administrator Date

PERSONNEL AUTHORIZED TO PERFORM PROCEDURE

NAME	DATE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____

LASER HAIR REMOVAL - POST TREATMENT INSTRUCTIONS

- Apply cool pack to treated site immediately after treatment if needed.
- Bathe/shower with warm water for the first two days after a treatment. Use gentle, non-abrasive cleanser that is free of artificial fragrance, detergent, color and oil. Avoid exfoliating the skin with loofas or abrasive scrubs.
- Do not use hot water or “soak” in the tub. Avoid Jacuzzis and saunas.
- No strenuous exercise for 48 hours.
- If scabs appear after blistering, they should be kept soft with a lubricating cream. Blistered or ulcerated skin may be treated with an antibiotic ointment or burn treatment cream.
- Facial treatment(s) may use an oil-free, non-medicated cover up, preferably one with sunscreen. Avoid use of toners for 48 hours. Thereafter, toners that contain the complete group of antioxidant vitamins A, C, and E may be used. Chemical peels are not recommended throughout the treatments.
- Apply 1% hydrocortisone cream to the treated area every 12-hours for the first 48-hours after treatment if instructed by personnel. Moisturize with Aloe Vera gel or light fragrance-free moisturizer, after the first 48 hours.
- Avoid using skin irritants, Retina-A, Benzyl Peroxide, Glycolic Acid, and astringents on the treated areas. Avoid deodorant for 48 hours if the underarm area was treated.
- Avoid exposure to the sun. Wear protective clothing and use sun block SPF 30 or higher, daily throughout the treatment process [5-8 months]. A good sun block will contain zinc oxide or titanium dioxide and will protect against both UVA and UVB rays. Tanning after treatment may cause hyper-pigmentation.
- Refrain from shaving treated area. Waxing and plucking may delay future treatment(s). It will take longer for the hair to reappear.
- Patients who tend to sunburn rather than tan, usually obtain good results on the first and subsequent visits.

Note: Possible side effects of treatment may include redness, local swelling, dry skin, mild tenderness or whitehead-like bumps. Symptoms may be present immediately or appear several days after treatment.

FITZPATRICK CLASSIFICATION FOR SKIN TYPES

PATIENT SKIN TYPE

Proper patient assessment and patient selection is the key to successful Laser Hair Removal. It is important to factor in the effect of the patient's skin type. People are divided into different skin types based upon the amount of melanin content in the skin and on the capacity of the skin to produce melanocytes in response to sunlight.

The licensed medical personnel shall classify the patient's skin type [using the below chart] in order to properly set the Laser parameters prior to a procedure.

SKIN TYPE	COLOR	REACTION TO UVA	REACTION TO SUN
Type I	Caucasian – blond or red hair, freckles, fair skin, blue eyes	Very Sensitive	Always burns easily, never tans, fair skin tone
Type II	Caucasian - blond or red hair, freckles, fair skin, blue or green eyes	Very Sensitive	Usually burns easily, tans with difficulty, fair skin tone
Type III	Darker Caucasian, light Asian	Sensitive	Burns moderately, tans gradually, fair to medium skin tone
Type IV	Mediterranean, Asian, Hispanic	Moderately Sensitive	Rarely burns, always tans well, medium skin tone
Type V	Middle Eastern, Latin, light-skinned Black, Indian	Minimally Sensitive	Very rarely burns, tans very easily, olive or dark skin tone
Type VI	Dark-skinned Black	Least Sensitive	Never burns, deeply pigmented, very dark skin tone

Note: A notification to the Medical Director for concurrence may be advisable for client's requesting higher power settings.

POTENTIALLY PHOTOSENSITIZING MEDICATIONS

Acne Meds
Isotretinoin (Accutane) Tretinoin (Retin-A)

Anticancer
Chlorambucil Cyclophosphamide
Dacarbazine Fluorouacil
Flutamide Mercaptopurine
Methotrexate Procarbazine
Thioguanine Vinblastine

Antidepressants
Amitriptyline Amoxapine
Clomipramine Doxepin
Imipramine Isocarboxazid
Maprotiline Phenelzine
Protriptyline Trazadone
Trimipramine

Antiepileptics, Sedative, Muscle Relaxants
Carbamazepine Cyclobenzaprine
Diazepam Meprobamate
Phenobarbitol Phenytoin

Antihistamines
Azatadine Clemastine
Diphenhydramine Terfenadine
Tripelennamine

Antihypertensives
Captopril Dilitiazem
Methyldopa Minoxidil
Nifedipine

Antimicrobials
Ciprofloxacin Clofazimine
Dapsone Demeclocycline
Doxycycline Enoxacine
Flucytosine Griseafulvin
Ketoconazole Lomefloxacine
Methacycline Minocycline
Nalidixic acid Narfloxacin
Ofloxacin Oxytetracycline
Pyrazinamide

Sulfa drugs
(Bactrim, Septra,Tetracycline)

Antiparasitics
Bithionol Chloroquine
Pyrvinium pamoate Quinine
Thiabendazole

Antipsychotics
Chlorpromazine Chlorprothixene
Fluphenazine Haloperidol
Perphenazine Prochlorperazine
Promethazine Thioridazine
Thiothixene Trifluoperazine
Thioflupromazine Trimeprazine

Cardiovascular
Amiodarone Atenolol
Captopril Diltiazem
Disopyramide Nifedipine
Propranolol Quinidine gluconate
Quinidine sulfate Verapamil

Diuretics
Acetazolamide Amiloride
Bendroflumethiazide Benzthiazide
Chlorothiazide Furosemide
Hydrochlorothiazide Hydro flumethiazide
Methyclothiazide Metolazone
Polythiazide Quinethazone
Trichlormethia-zide

Hypoglycemics
Acetohexamide Chlorpropamide
Glipizide Tolazamide
Tolbutamide

NSAIDS
Diclofenac Fenoprofen
Flurbiprofen Indomethacin
Ketoprofen Meclofenamate
Naproxen Phenylbutazone
Piroxicam Sulindac

Others
Bergamot oil Oils of citron, lavender, lime, sandalwood
Benzocaine Clofibrate Oral contraceptive
Etretinate Gold salts
Hexachlorophene Lovastatin
St John’s Wort Methylcoumarin (used in perfumes, lotions, etc)

PURPOSE

To ensure safe and effective treatment of clients undergoing Intense Pulse Light [IPL] administration at the [**INSERT PRACTICE NAME**], the following policies and procedures have been developed.

POLICY

A Registered Nurse [RN], Physician Assistant or licensed medical personnel with current state licensure shall be able to assess, consult and treat clients with IPL following the guidelines set herein.

SETTING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel can perform the administration of IPL in various settings and locations, such as but not limited to:

- Physician Office
- Satellite clinic / health care office(s)
- Medspa Setting authorized by the Medical Director
- Health Club Setting[19] authorized by the Medical Director

All IPL procedures shall be performed in a clean, safe environment properly equipped with universal precautions in place.

SUPERVISION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary.

All adverse reactions such as pain, skin redness [erythema], damage to natural skin texture [crust, blister, or burn], scarring, permanent discoloration, excessive swelling [edema], fragile skin, and/or bruising shall be reported immediately to the Medical Director. Side effects may appear either at the time of treatment or shortly thereafter. Adverse reaction(s) shall be documented in the client's chart.

[19] California Business & Professions Code Section 2725 and California Code of Regulations, Section 1470-1474; Health Club Setting does not meet California performance standards. May apply in other states.

PATIENT CONDITIONS

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will not knowingly treat clients' with / on / using:

- Malignant or pre-malignant pigmented lesions.
- Photosensitive medications [i.e. Retin A, Alpha Hydroxyl or Glycolic Acid].
- Pregnancy.
- Known anticoagulative or thromboembolic condition.
- Diabetes [Type I or II].
- Scarring or infection of the area to be treated.
- Pacemaker or internal defibrillator
- Use of Isotrentinoin [Accutane®] within past 6 months.
- Use of anticoagulation medication.
- Presence of a deep suntan, sunburn or artificially toned skin.

TREATMENT CONSIDERATIONS

- The focus of skin rejuvenation is for full-face treatments. However, this procedure may also be performed for photo damaged and aged neck, chest, arms, and hands.
- Indications for skin rejuvenation are: vascular lesions such as telangiectasias, angiomas, spider veins, pigmented lesions such as solar letingines, age spots, freckles, and textural irregularities such as rough skin, or fine lines.
- Select clients with skin types I-IV.
- Before and after photographs are helpful and will allow client(s) to view results.

INTENSE PULSE LIGHT PROCEDURE

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

1. Complete / update the client's medical / physical history.

2. Exclude those having contraindications for treatment.

3. Determine the client's expectations and reason(s) for seeking treatment. Advise client about treatment arrangement, typical results, and possible adverse effects and discomfort.

4. Remove all make-up, lotion, perfume, deodorant, and sunscreen.

5. If there is pigmented hair in the treatment area, clip down to skin surface. These hairs may become reduced or miniaturized.

6. Instruct client about laser safety precautions [refer to Safety Procedures].

7. Apply protective eyewear.

8. Apply clear conductive gel to treatment area.

9. Test optical fluences within appropriate range for the skin type [reference guidelines IPL Parameters].

10. Titrate optical fluences within appropriate range for testing. Clearly landmark the test spot areas, wait 5-10 minutes to determine therapeutic treatment parameters.

11. Treat with the highest tested optical fluence that does not leave prolonged diffuse epidermal erythema after waiting 5-10 minutes.

12. The treatment head should be floated in a layer of gel of between 2-4mm for most treatments. If deeper penetration is required, apply even pressure [with applicator] on to skin before pulsing, there should be slight compression of skin. Visually inspect that there is full contact of applicator.

13. Placement of the pulses should be overlapped making footprints in gel. This will ensure good surface coverage of the treatment area.

Note: The following immediate response for vascular lesions may be observed:
Erythema, loss of demarcation, vessel changes color or no refilling of vessel.

OR

The following immediate response for pigmented lesions may be observed:
Erythema, edema or lesion changes color.

Note: If the skin shows no adverse effects and there are no visible changes in lesion, then **increase** fluence. If the skin shows adverse effects, then **reduce** fluence. After adjusting the fluence, evaluate the treatment site for visible effects. If the lesion shows evidence of energy absorption, continue treatment at those parameters.

First treatment(s) of pigmented lesion, adjust treatment to get appropriate response for darker spots. Subsequent visits will concentrate on light spots.

Where there are a combination of vascular and pigmented lesion at the same site, start treatment from pigmented lesion. Subsequent visits will treat vascular lesion, which usually requires higher fluence.

14. Remove gel following treatment. Cool damp gauze may be used to rinse gel residue. If any epidermal effects develop, apply cooling from gel pack. Apply mild hydrocortisone if necessary. Always apply sunscreen if client is going outside during daylight hours.

15. Parameters for follow-up treatment(s) should be based on tissue reaction from previous treatment, compliance with sun avoidance, and any changes in medical condition. If no adverse reaction resulted, try testing optical fluence 1-2 J/cm2 higher.

Note: Generally several treatments are necessary to produce results. The average number of treatment(s), for each site treated, is between 3 and 5. Treatments should be spaced between 3-4 weeks. Skin texture may not change immediately. Clients' should allow at least two weeks to see results.

Some client(s) may benefit from the application of topical anesthetics prior to procedure. A topical anesthetic should be chosen that does not cause vasoconstriction.

SAFETY PROCEDURES

A well-trained staff primarily assures patient safety. In an effort to protect both the operator and client, the following safety measures[20] shall be observed:

- Operator(s) [physician(s) and staff personnel] shall familiarize themselves with equipment documentation and accompanying materials. Only properly trained operators' will be permitted to operate IPL equipment.
- Operator(s) shall know how to initiate emergency shut off procedures.
- Do not use IPL in the presence of explosive anesthetics or other flammable materials.
- Do not leave key in an unattended system.
- Do not expose any skin except the test and treatment area to the pulsed light.
- Corneal shields shall be placed on client's eyes prior to the procedure.
- Protective eyewear shall be available at all entrances to treatment room(s). Anyone wishing to enter a treatment room during a procedure shall knock appropriately and don protective eyewear prior to opening the door.
- Treatment room(s) shall be clearly marked with appropriate signs indicating the use of Intense Pulsed Device.
- If alcohol is used for cleaning and disinfecting, it must be allowed to dry thoroughly before the system is used.
- All windows shall be covered. Operator(s) shall not allow reflective objects such as jewelry, watches, surgical instruments or mirrors to intercept the laser.
- Wet towels shall be available in the treatment room in case of fire.

NOTE: Light penetration through the skin is wavelength-dependent, whereas photon energy is inversely proportional to wavelength. Longer wavelengths penetrate deeply and have lower energy; shorter wavelengths have higher energy and reach more shallow targets. Therefore, the choice of filter depends on the clinical indication. As a general rule, for Fitzpatrick skin types I to III the 560nm and 590nm filters should be used. Treatments for Fitzpatrick skin type IV to VI should be performed using a 640nm filter to decrease the risk of side-effects to the skin.

[20] OSHA [Occupational Safety & Health Administration] Publication 8-1.7 Guidelines for Laser Safety and Hazard Assessment.

Insert manufacturer protocol here including laser settings for the various Fitzpatrick skin types as well as any special considerations by the manufacturer for the machine to be utilized.

ENVIRONMENTAL CONCERNS

- Corrosive material may damage electronic parts. Operate the IPL system in a non-corrosive atmosphere.

- Metallic dust can damage electrical equipment. Particle dust absorbs light and heats up. Hot particles located on the optical light guide can damage it, particle dust should be kept to a minimum.

- For optimal system operation maintain room temperature between 20-25 degrees C [68-77 degrees F] and relative humidity of less than 80%.

POTENTIALLY PHOTOSENSITIZING MEDICATIONS

Acne Meds
Isotretinoin (Accutane) Tretinoin (Retin-A)

Anticancer
Chlorambucil Cyclophosphamide
Dacarbazine Fluorouacil
Flutamide Mercaptopurine
Methotrexate Procarbazine
Thioguanine Vinblastine

Antidepressants
Amitriptyline Amoxapine
Clomipramine Doxepin
Imipramine Isocarboxazid
Maprotiline Phenelzine
Protriptyline Trazadone
Trimipramine

Antiepileptics, Sedative, Muscle Relaxants
Carbamazepine Cyclobenzaprine
Diazepam Meprobamate
Phenobarbitol Phenytoin

Antihistamines
Azatadine Clemastine
Diphenhydramine Terfenadine
Tripelennamine

Antihypertensives
Captopril Dilitiazem
Methyldopa Minoxidil
Nifedipine

Antimicrobials
Ciprofloxacin Clofazimine
Dapsone Demeclocycline
Doxycycline Enoxacine
Flucytosine Griseafulvin
Ketoconazole Lomefloxacine
Methacycline Minocycline
Nalidixic acid Narfloxacin
Ofloxacin Oxytetracycline
Pyrazinamide

Sulfa drugs
(Bactrim, Septra,Tetracycline)

Antiparasitics
Bithionol Chloroquine
Pyruvinium pamoate Quinine
Thiabendazole

Antipsychotics
Chlorpromazine Chlorprothixene
Fluphenazine Haloperidol
Perphenazine Prochlorperazine
Promethazine Thioridazine
Thiothixane Trifluoperazine
Thioflupromazine Trimeprazine

Cardiovascular
Amiodarone Atenolol
Captopril Diltiazem
Disopyramide Nifedipine
Propranolol Quinidine gluconate
Quinidine sulfate Verapamil

Diuretics
Acetazolaminde Amiloride
Bendroflumethiazide Benzthiazide
Chlorothiazide Furosemide
Hydrochlorothiazide Hydro flumethiazide
Methyclothiazide Metalazone
Polythiazide Quinethazone
Trichlormethia-zide

Hypoglycemics
Acetohexamide Chlorpropamide
Glipizide Tolazamide
Tolbutamide

NSAIDS
Diclofenac Fenoprofen
Flurbiprofen Indomethacin
Ketoprofen Meclofenamate
Naproxen Phenylbutazone
Piroxicam Sulindac

Others
Bergamot oil Oils of citron, lavender, lime, sandalwood
Benzocaine Clofibrate Oral contraceptive
Etretinate Gold salts
Hexachlorophene Lovastatin
St John’s Wort Gmethylcoumarin (used in perfumes, lotions, etc)

RECORD KEEPING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall be responsible for maintaining client records, including but not limited to client assessment, signed informed consent of risks, benefits, and potential adverse effects, number of treatments, and the client response to treatment including the quality of skin, pigmentation changes.

REQUIREMENTS FOR REGISTERED NURSE

TRAINING / EDUCATION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall receive specialized training [and be certified] in the administration of IPL A Medical Doctor, Doctor of Osteopath, Advanced Registered Nurse Practitioner experienced in this procedure, or a teaching institution specializing in this procedure, may perform this training and certification. Competencies to successfully demonstrate shall include:

- Mechanism of Action of Intense Pulse Light
- Preparation of the skin
- Safety, efficacy, and complication issues
- Assessment and identification of areas to be treated
- Safe application of Intense Pulse Light technique [minimum 8-hours hands on training]

NOTE: IPL may only be performed by a physician, physician assistant and/or registered nurse[21]. Unlicensed personnel, including medical assistants may not perform any type of Intense Pulse Light.[22]

COMPETENCIES and DOCUMENTATION

The Medical Director and/or [applicable licensure], shall

- Document [on the appropriate form] the initial evaluation and final determination recording satisfactory completion of training and competence.

- Evaluate the competence of the Registered Nurse [RN], Physician Assistant or licensed medical personnel on an annual basis and/or as needed if indicated by client dissatisfaction or efficacy issues.

- The evaluation shall be maintained in the personnel file of the Registered Nurse [RN], Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].

[21] Business & Professions Code, Section 2725(b)(4), (c) provides the statutory authority for registered nurses to perform medical functions pursuant to standardized procedures.
[22] California Business & Professions Code, Section(s) 2069-2071 and Title 16 California Code of Regulations, Section(s) 1366-1366.4. Reference: Use of Lasers, Dermabrators, Botox and Other Treatments by Non-Physicians, Medical Board of California Action Report, page 6, October 2012.

DEVELOPMENT & APPROVAL OF STANDARDIZED PROCEDURE

The Standardized Procedure and Protocol for the Administration of Intense Pulse Light [IPL] has been developed jointly by the Medical Director, Administrator, and the Registered Nurse. This protocol shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

_____ _____
Nurse Date

_____ _____
Medical Director Date

_____ _____
Administrator Date

PERSONNEL AUTHORIZED TO PERFORM PROCEDURE

NAME	DATE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____

INTENSE PULSED LIGHT - POST TREATMENT INSTRUCTIONS

- Apply cool pack [not frozen] to treated site immediately after treatment.
- The first five-days following treatment, care should be taken to prevent trauma to the treated site. Avoid hot baths, massage, and exercising.
- If scabs appear after blistering, they should be kept soft with a lubricating cream. Blistered or ulcerated skin may be treated with an antibiotic ointment [Aquaphor] or burn treatment cream. If crusting occurs, avoid picking at it. Picking can cause scarring. Once the scab falls off the skin may be lighter, or darker. This usually resolves over a few months. There will be an obvious color difference from the unburned skin.
- Apply 1% hydrocortisone cream to the treated area every 12-hours for the first 48-hours after treatment.
- Moisturize with Aloe Vera gel or any light fragrance-free moisturizer, after the first 48 hours.
- Avoid using skin irritants, Retina-A, Benzyl Peroxide, Glycolic Acid, and astringents on the treated areas. Chemical peels are not recommended throughout treatment series.
- Use high factor sunscreen, SPF 30 or higher. A good sun block will contain zinc oxide or titanium dioxide and will protect against both UVA and UVB rays. Tanning after treatment may cause hyper-pigmentation.
- Fillers or other injectibles should not be done within 2 weeks before/after treatment.

FITZPATRICK CLASSIFICATION FOR SKIN TYPES

PATIENT SKIN TYPE

Proper patient assessment and patient selection is the key to successful Laser Hair Removal. It is important to factor in the effect of the patient's skin type. People are divided into different skin types based upon the amount of melanin content in the skin and on the capacity of the skin to produce melanocytes in response to sunlight.

The RN, PA or licensed medical personnel shall classify the patient's skin type [using the below chart] in order to properly set the Laser parameters prior to a procedure.

SKIN TYPE	COLOR	REACTION TO UVA	REACTION TO SUN
Type I	Caucasian – blond or red hair, freckles, fair skin, blue eyes	Very Sensitive	Always burns easily, never tans, fair skin tone
Type II	Caucasian - blond or red hair, freckles, fair skin, blue or green eyes	Very Sensitive	Usually burns easily, tans with difficulty, fair skin tone
Type III	Darker Caucasian, light Asian	Sensitive	Burns moderately, tans gradually, fair to medium skin tone
Type IV	Mediterranean, Asian, Hispanic	Moderately Sensitive	Rarely burns, always tans well, medium skin tone
Type V	Middle Eastern, Latin, light-skinned Black, Indian	Minimally Sensitive	Very rarely burns, tans very easily, olive or dark skin tone
Type VI	Dark-skinned Black	Least Sensitive	Never burns, deeply pigmented, very dark skin tone

FITZPATRICK SKIN TYPE FORM

Help Us Treat You the Right Way.....
Skin type is often categorized according to the Fitzpatrick Skin Type Scale which ranges from very fair (skin type I) to very dark (skin type VI). Genetic disposition, individual reaction to sun exposure and tanning habits are considered. **Please mark the Score (0-4) and then add the scores on the right side of the page.**

Genetic Disposition

What is the color of your eyes?
0 –Light blue\Gray\Green **1** – Blue\Gray\Green **2** – Blue **3** – Dark Brown **4** – Brownish Black **Score: _____**

What is the natural color of your hair?
0 – Sandy Red **1** – Blonde **2** – Auburn/ light Blonde **3** – Dark Brown **4** – Black **Score: _____**

What is the color of your skin (non-exposed areas)?
0 – Reddish **1** – Very Pal e **2** – Pale w/Beige Tint **3** – Light Brown **4** – Dark Brown **Score: _____**

Do you have freckles on unexposed skin?
0 – Many **1** – Several **2** – Few **3** – Incidental **4** – None **Score: _____**

Total Score for Genetic Disposition: _____

Reaction to Sun Exposure

What happens when you stay too long in the sun?
0 – Painful redness, blistering, peeling **1** – Moderate redness, blistering followed by peeling
2 – Mild burn sometimes followed by peeling **3** – Rare Burns **4** – Never had burns **Score: _____**

To what degree do you turn brown?
0 – Never **1** – Light color tan **2** – Reasonable tan **3** – Tan easy **4** – Tans darkly quickly **Score: _____**

Do you turn brown within several hours after sun exposure?
0 – Never **1** – Seldom **2** – Sometimes **3** – Often **4** – Always **Score: _____**

How does your face react to the sun?
0 – Sensitive **1** – Seldom **2** – Sometimes **3** – Normal **4** – Resistant **Score: _____**

Total score for Reaction to Sun Exposure: _____

Tanning Habits

How many months ago was your body last exposed to sun, tanning light or tanning cream?
0 – More than 3 months **1** – 2-3months **2** – 1-2months **3** – Less than a month **4** – 2 weeks **Score: _____**

Has the area to be treated ever been exposed to the sun?
0 – Never **1** – Seldom **2** – Sometimes **3** – Often **4** – Always **Score: _____**

Total score forTanning Habits: _____

Skin type score	Fitzpatrick Skin Type
0 to 7	I
8 to 16	II
17 to 25	III
25 to 30	IV
over 30	V – VI

Total score of 3 sections: _____

Fitzpatrick SKIN TYPE _____

_____ Client
[Print Name] Signature Date

_____ Witness
[Print Name] Signature Date

Confidential Skin Health Survey

Please Print: Today's Date _____

First Name _____

Last Name _____ Date of Birth ___/___/___

Address _____ Apt. # _____

City _____ State _____ Zip_____

Phone H (____) _____ Work (____) _____

Cell (_____) _____

Dermatologist/Physician _____

Phone (____) _____

Emergency Contact _____

Phone (____) _____

Your Occupation _____

Email _____

Referred By
 Friend Mailer Newspaper Magazine Ad other

Esthetician Name _____

1. Is this your first facial?
 Yes No
2. What is the reason for your visit today?
 Tazarac Glycolic or Alpha-hydroxy Acids
3. What special areas of concern do you have?
 _____
4. Are you presently under a physician's care for any current skin condition or other problem?
 Yes No
 Please Describe_____
5. Are you pregnant?
 Yes No
6. Are you taking birth control pills?
 Yes No
7. Hormone replacement?
 Yes No
 Please list _____
8. Do you wear contact lenses?
 Yes No
9. Do you smoke?
 Yes No
10 Do you often experience stress?
 Yes No
11. Have you had skin cancer?

 Yes No

12. What products do you use presently?

 Soap Cleansing milk Toner Scrub Mask Creams
 Sunscreen Other

13. Are you now using (or used in the past):

 Azelex Differin Renova Retin-A

If so, when and for how long?_____

14. Are you now using or have you ever used Accutane?

 Yes No

If so, when and for how long? _____

15. Do you have acne?

 Yes No

Experience frequent blemishes?

 Yes No

15. Do you have any allergies to cosmetics, foods, or drugs?

 Yes No

If so, what type? _____

16. Are you presently taking medications –oral or topical?

 Yes No

If so, what type? _____

Please circle if you are affected by or have any of the following:

Asthma	Hepatitis	Metal bone, pins, or plates
Cardiac problems	Herpes	Pacemaker
Eczema	High blood pressure	Psychological problems
Epilepsy	Hysterectomy	Sinus problems
Fever blisters	Immune disorders	Skin diseases –other
Headaches-chronic	Lupus	Urinary or kidney problems

Please explain above problems or list any significant others:

_____

I understand that the services offered are not a substitute for medical care, and any information provided by the aesthetician or other licensed medical professional is for educational purpose only and not diagnostic or prescriptive in nature. I understand that the information contained is to aid the aesthetician or other licensed medical professional in giving better service and is completely confidential.

Policies:

1. Professional consultation is required before initial dispensing of products.
2. We do not give cash refunds and we require a 24-hour cancellation notice.

I fully understand and agree to the above policies.

_____ _____

Patient Signature Date

PURPOSE

To ensure safe and effective treatment of clients undergoing Light Energy Skin Tightening administration at the [**INSERT PRACTICE NAME**], the following policies and procedures have been developed.

POLICY

A Registered Nurse [RN], Physician Assistant or licensed medical personnel with current state licensure shall be able to assess, consult and treat clients with IPL following the guidelines set herein.

SETTING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel can perform the administration of IPL in various settings and locations, such as but not limited to:

- Physician Office
- Satellite clinic / health care office(s)
- Medspa Setting authorized by the Medical Director
- Health Club Setting[23] authorized by the Medical Director

All RF and Non-Ablative light energy procedures shall be performed in a clean, safe environment properly equipped with universal precautions in place.

SUPERVISION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary.

All adverse reactions such as pain, skin redness [erythema], damage to natural skin texture [crust, blister, or burn], scarring, permanent discoloration, excessive swelling [edema], fragile skin, and/or bruising shall be reported immediately to the Medical Director. Side effects may appear either at the time of treatment or shortly thereafter. Adverse reaction(s) shall be documented in the client's chart.

PATIENT CONDITIONS

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will not knowingly treat clients' with / on / using:

- Malignant or pre-malignant pigmented lesions.

[23] California Business & Professions Code Section 2725 and California Code of Regulations, Section 1470-1474; Health Club Setting does not meet California performance standards. May apply in other states.

- Photosensitive medications [i.e. Retin-A, Alpha Hydroxyl or Glycolic Acid], see attached list for additional medications.
- Pregnancy.
- Known anticoagulative or thromboembolic condition.
- Diabetes [Type I or II].
- Scarring or infection of the area to be treated.
- Pacemaker or internal defibrillator
- Use of Isotrentinoin [Accutane®] within past 6 months.
- Use of anticoagulation medication.
- Presence of a deep suntan, sunburn or artificially toned skin.

TREATMENT CONSIDERATIONS

- The focus of skin rejuvenation is for full-face treatments. However, this procedure may also be performed for photo damaged and aged neck, chest, arms, and hands.
- Indications for skin rejuvenation are: vascular lesions such as telangiectasias, angiomas, spider veins, pigmented lesions such as solar letingines, age spots, freckles, and textural irregularities such as rough skin, or fine lines.
- Select clients with skin types I-IV or possibly skin type V if the device has long pulse capabilities.
- Before and after photographs are helpful and will allow client(s) to view results.

SKIN TIGHTENING PROCEDURE

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

1. Complete / update the client's medical / physical history.

2. Exclude those having contraindications for treatment.

3. Determine the client's expectations and reason(s) for seeking treatment. Advise client about treatment arrangement, typical results, and possible adverse effects and discomfort.

4. Remove all make-up, lotion, perfume, deodorant, and sunscreen, thoroughly clean and dry the skin before treatment.

5. Establish the appropriate energy settings by referring to the manufacturer's guide.

6. Instruct client about laser safety precautions [refer to Safety Procedures].

7. Apply protective eyewear.

8. Mark areas (quadrants) to determine optimal skin tightening effect – see attached charting.

9. Test optical fluences within appropriate range for the skin type [reference guidelines for RF, Ultrasound or Infrared Device Parameters].

10. Titrate optical fluences within appropriate range for testing per manufacturer specifications. Clearly landmark the test spot areas, wait 5-10 minutes to determine therapeutic treatment parameters.

11. Treat with the highest tested optical fluence that does not leave prolonged diffuse epidermal erythema after waiting 5-10 minutes.

12. For most devices multiple passes need to be administered to ensure enough light energies to be absorbed within the skin. If deeper penetration is required, apply additional passes over the treatment area, skin should have an endpoint of erythema. For various devices that do not specify the number of pulses over the area, patient response to pain will be used to determine number of passes with the laser light energy attachment.

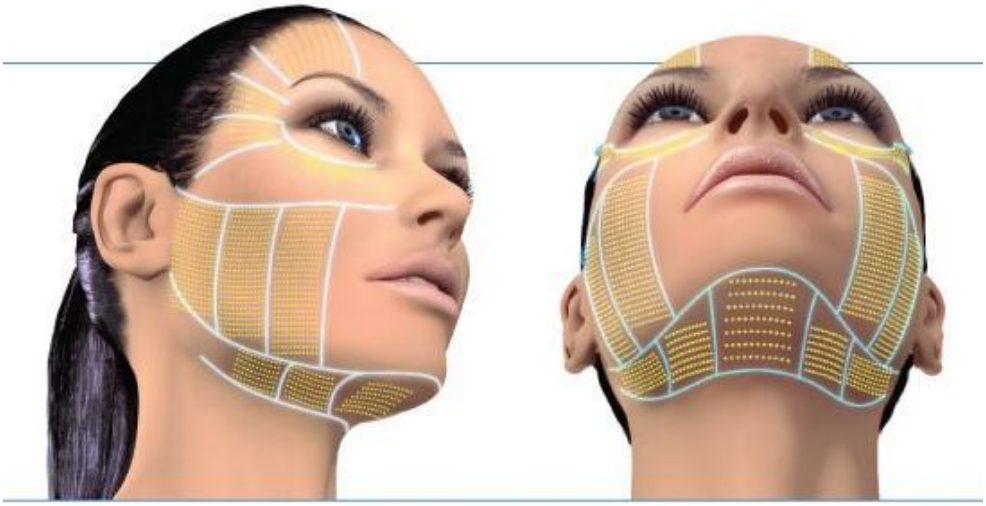
13. Placement of the pulses should be in a fanning pattern with very little overlap of pulses with each pass, his will ensure good surface coverage of the treatment area.

Note: If the skin shows no adverse effects and there are no visible changes to the skin (erythema), then **increase** fluence. If the skin shows adverse effects, then **reduce** fluence. After adjusting the fluence, evaluate the treatment site for visible effects. If the skin shows evidence of energy absorption (erythema), continue treatment at those parameters.

14. Remove gel following treatment. Cool damp gauze may be used to rinse gel residue. If any epidermal effects develop, apply cooling from gel pack. Apply mild hydrocortisone if necessary. Always apply sunscreen if client is going outside during daylight hours.

15. Parameters for follow-up treatment(s) should be based on tissue reaction from previous treatment, compliance with sun avoidance, and any changes in medical condition. If no adverse reaction resulted from prior treatment, titration of light energies can be achieved using manufacturer recommendations.

Note: Generally several treatments are necessary to produce results. The average number of treatment(s), for each site treated, is between 3 and 5. Treatments should be spaced between 3-4 weeks. Skin texture may not change and client should allow at least two to three weeks to see results.



Treatment Areas – Quadrants of the Face

SAFETY PROCEDURES

A well-trained staff primarily assures patient safety. In an effort to protect both the operator and client, the following safety measures[24] shall be observed:

- Operator(s) [physician(s) and staff personnel] shall familiarize themselves with equipment documentation and accompanying materials. Only properly trained operators' will be permitted to operate IPL equipment.
- Operator(s) shall know how to initiate emergency shut off procedures.
- Do not use IPL in the presence of explosive anesthetics or other flammable materials.
- Do not leave key in an unattended system.
- Do not expose any skin except the test and treatment area to the pulsed light.
- Corneal shields shall be placed on client's eyes prior to the procedure.
- Protective eyewear shall be available at all entrances to treatment room(s). Anyone wishing to enter a treatment room during a procedure shall knock appropriately and don protective eyewear prior to opening the door.
- Treatment room(s) shall be clearly marked with appropriate signs indicating the use of Intense Pulsed Device.
- If alcohol is used for cleaning and disinfecting, it must be allowed to dry thoroughly before the system is used.

NOTE: Light penetration through the skin is wavelength-dependent, whereas photon energy is inversely proportional to wavelength. Longer wavelengths penetrate deeply and have lower energy; shorter wavelengths have higher energy and reach more shallow targets. Therefore, the type of laser light energy will have different settings. Skin Tightening Treatments are typically safe for all skin types, however Fitzpatrick skin type IV to VI should be given a test patch per procedure to determine tolerance and any other symptoms (i.e. excessive erythema) that would preclude them from the procedure.

[24] OSHA [Occupational Safety & Health Administration] Publication 8-1.7 Guidelines for Laser Safety and Hazard Assessment.

Insert manufacturer protocol here including laser settings for the various Fitzpatrick skin types as well as any special considerations by the manufacturer for the machine to be utilized.

ENVIRONMENTAL CONCERNS

- Corrosive material may damage electronic parts. Operate all laser light energy devices in a non-corrosive atmosphere.

- Metallic dust can damage electrical equipment. Particle dust absorbs light and heats up. Hot particles located on the optical light guide can damage it, particle dust should be kept to a minimum.

- For optimal system operation maintain room temperature between 20-25 degrees C [68-77 degrees F] and relative humidity of less than 80%.

POTENTIALLY PHOTOSENSITIZING MEDICATIONS

Acne Meds
Isotretinoin (Accutane) Tretinoin (Retin-A)

Anticancer
Chlorambucil Cyclophosphamide
Dacarbazine Fluorouacil
Flutamide Mercaptopurine
Methotrexate Procarbazine
Thioguanine Vinblastine

Antidepressants
Amitriptyline Amoxapine
Clomipramine Doxepin
Imipramine Isocarboxazid
Maprotiline Phenelzine
Protriptyline Trazadone
Trimipramine

Antiepileptics, Sedative, Muscle Relaxants
Carbamazepine Cyclobenzaprine
Diazepam Meprobamate
Phenobarbitol Phenytoin

Antihistamines
Azatadine Clemastine
Diphenhydramine Terfenadine
Tripelennamine

Antihypertensives
Captopril Dilitiazem
Methyldopa Minoxidil
Nifedipine

Antimicrobials
Ciprofloxacin Clofazimine
Dapsone Demeclocycline
Doxycycline Enoxacine
Flucytosine Griseafulvin
Ketoconazole Lomefloxacine
Methacycline Minocycline
Nalidixic acid Narfloxacin
Ofloxacin Oxytetracycline
Pyrazinamide

Sulfa drugs
(Bactrim, Septra,Tetracycline)

Antiparasitics
Bithionol Chloroquine
Pyruvinium pamoate Quinine
Thiabendazole

Antipsychotics
Chlorpromazine Chlorprothixene
Fluphenazine Haloperidol
Perphenazine Prochlorperazine
Promethazine Thioridazine
Thiothixane Trifluoperazine
Thioflupromazine Trimeprazine

Cardiovascular
Amiodarone Atenolol
Captopril Diltiazem
Disopyramide Nifedipine
Propranolol Quinidine gluconate
Quinidine sulfate Verapamil

Diuretics
Acetazolaminde Amiloride
Bendroflumethiazide Benzthiazide
Chlorothiazide Furosemide
Hydrochlorothiazide Hydro flumethiazide
Methyclothiazide Metalazone
Polythiazide Quinethazone
Trichlormethia-zide

Hypoglycemics
Acetohexamide Chlorpropamide
Glipizide Tolazamide
Tolbutamide

NSAIDS
Diclofenac Fenoprofen
Flurbiprofen Indomethacin
Ketoprofen Meclofenamate
Naproxen Phenylbutazone
Piroxicam Sulindac

Others
Bergamot oil Oils of citron, lavender, lime, sandalwood
Benzocaine Clofibrate Oral contraceptive
Etretinate Gold salts
Hexachlorophene Lovastatin
St John’s Wort Gmethylcoumarin (used in perfumes, lotions, etc)

RECORD KEEPING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall be responsible for maintaining client records, including but not limited to client assessment, signed informed consent of risks, benefits, and potential adverse effects, number of treatments, and the client response to treatment including the quality of skin, erythema, and pigmentation changes.

REQUIREMENTS FOR REGISTERED NURSE

TRAINING / EDUCATION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall receive specialized training [and be certified] in the administration of skin tightening procedures for the specific device of the practice. A Medical Doctor, Doctor of Osteopath, Advanced Registered Nurse Practitioner experienced in this procedure, or a teaching institution specializing in this procedure, may perform this training and certification. Competencies to successfully demonstrate shall include:

- Mechanism of Action of Skin Tightening Procedures
- Preparation of the skin
- Safety, efficacy, and complication issues
- Assessment and identification of areas to be treated
- Safe application of the skin tightening light energy device technique [minimum 8-hours hands on training]

NOTE: Depending upon the classification of the skin tightening device, typically they may only be performed by a physician, physician assistant and/or registered nurse[25]. Unlicensed personnel may not perform any type of Skin Tightening Procedure.[26]

COMPETENCIES and DOCUMENTATION

The Medical Director and/or [applicable licensure], shall

- Document [on the appropriate form] the initial evaluation and final determination recording satisfactory completion of training and competence.

- Evaluate the competence of the Registered Nurse [RN], Physician Assistant or licensed medical personnel on an annual basis and/or as needed if indicated by client dissatisfaction or efficacy issues.

- The evaluation shall be maintained in the personnel file of the Registered Nurse [RN], Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].

[25] Business & Professions Code, Section 2725(b)(4), (c) provides the statutory authority for registered nurses to perform medical functions pursuant to standardized procedures.

[26] California Business & Professions Code, Section(s) 2069-2071 and Title 16 California Code of Regulations, Section(s) 1366-1366.4. Reference: Use of Lasers, Dermabrators, Botox and Other Treatments by Non-Physicians, Medical Board of California Action Report, page 6, October 2012.

DEVELOPMENT & APPROVAL OF STANDARDIZED PROCEDURE

The Standardized Procedure and Protocol for the Administration of skin tightening devices has been developed jointly by the Medical Director, Administrator, and the Registered Nurse. This protocol shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

_____ _____

Nurse Date

_____ _____

Medical Director Date

_____ _____

Administrator Date

PERSONNEL AUTHORIZED TO PERFORM PROCEDURE

NAME	DATE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____

Informed Consent for Laser Skin Tightening Treatments

INSTRUCTIONS
This is an informed consent document which has been prepared to help inform you about laser treatment procedures of skin, risks, and alternative treatments.

It is important that you read this information carefully and completely. Please sign each page, indicating that you have read the page and sign the consent for the procedure as proposed.

INTRODUCTION
Lasers have been used by physicians for many years. There are many different methods for the surgical use of lasers. Laser energy can be used to cut, vaporize, or selectively remove skin and deeper tissues.

Conditions such as wrinkles, sun damaged skin, unwanted hair, unsightly veins, acne scars, and some types of skin lesions/disorders may be treated with the laser. Certain surgical procedures may use the laser as a cutting instrument. In some situations, laser treatments may be performed at the time of other surgical procedures.

Skin treatment programs may be used both before and after laser skin treatments in order to enhance the results.

ALTERNATIVE TREATMENT
Alternative forms of treatment include not undergoing the proposed laser skin treatment procedure. Other forms of skin treatment (chemical peel) or surgical procedures may be substituted. In certain situations, the laser may offer a specific therapeutic advantage over other forms of treatment. Alternative methods for hair removal include: shaving, plucking, depilatory creams, waxing, electrolysis, or no treatment at all. Alternatively laser treatment procedures in some situations may not represent a better alternative to other forms of surgery or skin treatment when indicated. Risks and potential complications are associated with alternative forms of treatment that involve skin treatments or surgical procedures.

There are both risks and complications associated with all laser treatment procedures of the skin. Risks involve both items that specifically relate to the use of laser energy as a form of surgical therapy and to the specific procedure performed. An individual's choice to undergo a procedure is based on the comparison of risk to potential benefits. Although the majority of patients do not experience these complications, you should discuss each of them with your physician to make sure you understand the risks, potential complications and consequences of laser skin treatment.

Infection - Although infection following laser skin treatment is unusual, bacterial, fungal, and viral infections can occur. Herpes simplex virus infections around the mouth or other areas of the face can occur following a laser treatment. This applies to both individuals with a past history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications may be prescribed and taken both prior to and following the laser treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatments including antibiotics may be necessary.

Scarring - Although normal healing after the procedure is expected, abnormal scars may occur both in the skin and deeper tissues. In rare cases, keloid scars may result. Scars may be unattractive and of different color than the surrounding skin. Additional treatments may be needed to treat scarring.

Burns - Laser energy can produce burns. Adjacent structures including the eyes may be injured or permanently damaged by the laser beam. Burns are rare yet represent the effect of heat produced within the tissues by laser energy. Additional treatment may be necessary to treat laser bums.

Color Change - Laser treatments may potentially change the natural color of your skin. Skin redness usually lasts 2 weeks-3 months and occasionally 6 months following laser skin treatment. There is the possibility of irregular color variations within the skin including areas that are both lighter and darker. A line of demarcation between normal skin and skin treated with lasers can occur.

Accutane (Isotretinoln) - Accutane is a prescription medication used to treat certain skin diseases. This drug may impair the ability of skin to heal following treatments or surgery for a variable amount of time even after the patient has ceased taking it. Individuals who have taken the drug are advised to allow their skin adequate time to recover from Accutane before undergoing laser skin treatment procedures.

Skin Tissue Pathology - Laser energy directed at skin lesions may potentially vaporize the lesion. Laboratory examination of the tissue specimen may not be possible.

Visible Skin Patterns - Laser treatment procedures may produce visible patterns within the skin. The occurrence of this is not predictable.

Patient Failure to Follow Through - Patient follow through following a laser skin treatment procedure is important. Post-operative instructions concerning appropriate restriction of activity, use of dressings, and use of sun protection need to 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 laser skin treatment.

Damaged Skin - Skin that has been previously treated with chemical peels or dermabrasion, or damaged by bums, electrolysis (hair removal treatments), or radiation therapy may heal abnormally or slowly following treatment by lasers or other surgical techniques. The occurrence of this is not predictable. Additional treatment may be necessary.

Unsatisfactory Result - There is the possibility of an unsatisfactory result from these procedures. Laser procedures may result in unacceptable visible deformities, skin slough, loss of function, and permanent color changes in the skin. You may be disappointed with the final result from laser treatments.

Allergic Reactions - In rare cases, local allergies to tape, preservatives used in cosmetics or topical preparations have been reported. Systemic reactions which are more serious may result from drugs

used during medical procedures and prescription medicines. Allergic reactions may require additional treatment.

Lack of Permanent Results - Laser or other treatments may not completely improve or prevent future skin disorders, lesions, or wrinkles. Additional procedures or surgery may be necessary to further tighten loose skin.

Delayed Healing - It may take longer than anticipated for healing to occur after laser treatments. Skin healing may result in thin, easily injured skin. This is different from the normal redness in skin after a laser treatment.

Unknown Risks - There is the possibility that additional risk factors of laser skin treatments may be discovered.

Surgical Anesthesia - 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.

Additional Treatment or Surgery Necessary - There are many variable conditions which influence the long-term result of laser 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, procedures, 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.

FINANCIAL RESPONSIBILITIES

The cost of laser skin treatment involves several charges for the services provided. This includes fees charged by your doctor, the cost of pre and post-operative skin care medications, surgical supplies, laser equipment and personnel, laboratory tests, and possible outpatient hospital charges, depending on where the procedure is performed. It is unlikely that cosmetic surgery costs would be covered by an insurance plan. Even if there is some insurance coverage, you will be responsible for full payment. Additional costs may occur should complications develop from the treatment.

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. 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 physician 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.

INFORMED CONSENT FOR LASER & LIGHT BASED TREATMENTS

1. I hereby authorize [**Insert Practice Name**] certified personnel to perform the following laser light energy procedure and skin tightening treatments.

2. I recognize that during the course of the procedure and medical treatment, 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 has been given by anyone as to the results that may be obtained.

5. I consent to the photographing or televising of 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. 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 (1-6). I AM SATISFIED WITH THE EXPLANATION.

_____

Client [Print Name] Signature Date

_____

Witness [Print Name] Signature Date

SKIN TIGHTENING PROCEDURES
POST TREATMENT INSTRUCTIONS

- Apply cool pack [not frozen] to treated site immediately after treatment.

- The first five-days following treatment, care should be taken to prevent trauma to the treated site. Avoid hot baths, massage, and exercising.

- If scabs appear after blistering, they should be kept soft with a lubricating cream. Blistered or ulcerated skin may be treated with an antibiotic ointment [Aquaphor] or burn treatment cream. If crusting occurs, avoid picking at it. Picking can cause scarring. Once the scab falls off the skin may be lighter, or darker. This usually resolves over a few months. There will be an obvious color difference from the unburned skin.

- Apply 1% hydrocortisone cream to the treated area every 12-hours for the first 48-hours after treatment if prescribed by the physician.

- Moisturize with Aloe Vera gel or any light fragrance-free moisturizer, after the first 48 hours.

- Avoid using skin irritants, Retina-A, Benzyl Peroxide, Glycolic Acid, and astringents on the treated areas. Chemical peels are not recommended throughout treatment series.

- Use high factor sunscreen, SPF 30 or higher. A good sun block will contain zinc oxide or titanium dioxide and will protect against both UVA and UVB rays. Tanning after treatment may cause hyper-pigmentation.

- Fillers or other injectibles should not be done within 2 weeks before/after treatment.

FITZPATRICK CLASSIFICATION FOR SKIN TYPES

PATIENT SKIN TYPE

Proper patient assessment and patient selection is the key to successful Laser Hair Removal. It is important to factor in the effect of the patient's skin type. People are divided into different skin types based upon the amount of melanin content in the skin and on the capacity of the skin to produce melanocytes in response to sunlight.

The RN, PA or licensed medical personnel shall classify the patient's skin type [using the below chart] in order to properly set the Laser parameters prior to a procedure.

SKIN TYPE	COLOR	REACTION TO UVA	REACTION TO SUN
Type I	Caucasian – blond or red hair, freckles, fair skin, blue eyes	Very Sensitive	Always burns easily, never tans, fair skin tone
Type II	Caucasian - blond or red hair, freckles, fair skin, blue or green eyes	Very Sensitive	Usually burns easily, tans with difficulty, fair skin tone
Type III	Darker Caucasian, light Asian	Sensitive	Burns moderately, tans gradually, fair to medium skin tone
Type IV	Mediterranean, Asian, Hispanic	Moderately Sensitive	Rarely burns, always tans well, medium skin tone
Type V	Middle Eastern, Latin, light-skinned Black, Indian	Minimally Sensitive	Very rarely burns, tans very easily, olive or dark skin tone
Type VI	Dark-skinned Black	Least Sensitive	Never burns, deeply pigmented, very dark skin tone

FITZPATRICK SKIN TYPE FORM

Help Us Treat You the Right Way.....
Skin type is often categorized according to the Fitzpatrick Skin Type Scale which ranges from very fair (skin type I) to very dark (skin type VI). Genetic disposition, individual reaction to sun exposure and tanning habits are considered. **Please mark the Score (0-4) and then add the scores on the right side of the page.**

Genetic Disposition

What is the color of your eyes?
0 –Light blue\Gray\Green **1** – Blue\Gray\Green **2** – Blue **3** – Dark Brown **4** – Brownish Black **Score: _____**

What is the natural color of your hair?
0 – Sandy Red **1** – Blonde **2** – Auburn/ light Blonde **3** – Dark Brown **4** – Black **Score: _____**

What is the color of your skin (non-exposed areas)?
0 – Reddish **1** – Very Pal e **2** – Pale w/Beige Tint **3** – Light Brown **4** – Dark Brown **Score: _____**

Do you have freckles on unexposed skin?
0 – Many **1** – Several **2** – Few **3** – Incidental **4** – None **Score: _____**

Total Score for Genetic Disposition: _____

Reaction to Sun Exposure

What happens when you stay too long in the sun?
0 – Painful redness, blistering, peeling **1** – Moderate redness, blistering followed by peeling
2 – Mild burn sometimes followed by peeling **3** – Rare Burns **4** – Never had burns **Score: _____**

To what degree do you turn brown?
0 – Never **1** – Light color tan **2** – Reasonable tan **3** – Tan easy **4** – Tans darkly quickly **Score: _____**

Do you turn brown within several hours after sun exposure?
0 – Never **1** – Seldom **2** – Sometimes **3** – Often **4** – Always **Score: _____**

How does your face react to the sun?
0 – Sensitive **1** – Seldom **2** – Sometimes **3** – Normal **4** – Resistant **Score: _____**

Total score for Reaction to Sun Exposure: _____

Tanning Habits

How many months ago was your body last exposed to sun, tanning light or tanning cream?
0 – More than 3 months **1** – 2-3months **2** – 1-2months **3** – Less than a month **4** – 2 weeks **Score: _____**

Has the area to be treated ever been exposed to the sun?
0 – Never **1** – Seldom **2** – Sometimes **3** – Often **4** – Always **Score: _____**

Total score forTanning Habits: _____

Skin type score	Fitzpatrick Skin Type
0 to 7	I
8 to 16	II
17 to 25	III
25 to 30	IV
over 30	V – VI

Total score of 3 sections: _____

Fitzpatrick SKIN TYPE _____

_____ Client
[Print Name] Signature Date

_____ Witness
[Print Name] Signature Date

Confidential Skin Health Survey

Please Print: Today's Date _____

First Name _____

Last Name _____ Date of Birth ___/___/___

Address _____ Apt. # _____

City _____ State _____ Zip_____

Phone H (____) _____ Work (____) _____

Cell (_____) _____

Dermatologist/Physician _____

Phone (____) _____

Emergency Contact _____

Phone (____) _____

Your Occupation _____

Email _____

Referred By
 Friend Mailer Newspaper Magazine Ad other

Esthetician Name _____

1. Is this your first facial?
    Yes No
2. What is the reason for your visit today?
    Tazarac Glycolic or Alpha-hydroxy Acids
3. What special areas of concern do you have?
   _____
4. Are you presently under a physician's care for any current skin condition or other problem?
    Yes No
   Please Describe_____
5. Are you pregnant?
    Yes No
6. Are you taking birth control pills?
    Yes No
7. Hormone replacement?
    Yes No
   Please list _____
8. Do you wear contact lenses?
    Yes No
9. Do you smoke?
    Yes No

10 Do you often experience stress?
 Yes No
11. Have you had skin cancer?
 Yes No
12. What products do you use presently?
 Soap Cleansing milk Toner Scrub Mask Creams
 Sunscreen Other
13. Are you now using (or used in the past):
 Azelex Differin Renova Retin-A
If so, when and for how long?_____
14. Are you now using or have you ever used Accutane?
 Yes No
If so, when and for how long? _____
15. Do you have acne?
 Yes No
Experience frequent blemishes?
 Yes No
15. Do you have any allergies to cosmetics, foods, or drugs?
 Yes No
If so, what type? _____
16. Are you presently taking medications –oral or topical?
 Yes No
If so, what type? _____

Please circle if you are affected by or have any of the following:

Asthma	Hepatitis	Metal bone, pins, or plates
Cardiac problems	Herpes	Pacemaker
Eczema	High blood pressure	Psychological problems
Epilepsy	Hysterectomy	Sinus problems
Fever blisters	Immune disorders	Skin diseases –other
Headaches-chronic	Lupus	Urinary or kidney problems

Please explain above problems or list any significant others:

_____

I understand that the services offered are not a substitute for medical care, and any information provided by the aesthetician or other licensed medical professional is for educational purpose only and not diagnostic or prescriptive in nature. I understand that the information contained is to aid the aesthetician or other licensed medical professional in giving better service and is completely confidential.

Policies:
1. Professional consultation is required before initial dispensing of products.
2. We do not give cash refunds and we require a 24-hour cancellation notice.

I fully understand and agree to the above policies.

_____ _____
Patient Signature Date

COSMETIC “NON-ABLATIVE” LASER LIGHT ENERGY TREATMENTS

GENERAL CLINICAL POLICIES AND PROCEDURES

- Other Laser Applications (Other Indications for Use)

SECTION 10

PURPOSE

To ensure safe and effective treatment of clients undergoing other non-ablative type laser administration at the [**INSERT PRACTICE NAME**], the following policies and procedures have been developed.

POLICY

A Registered Nurse [RN], Physician Assistant or licensed medical personnel with current state licensure shall be able to assess, consult and treat clients with Hair Reduction Services using light energies (Laser Hair Removal) following the guidelines set herein.

SETTING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel can perform the administration of Hair Reduction Services using light energies (Laser Hair Removal) in various settings and locations, such as but not limited to:

- Physician Office
- Satellite clinic / health care office(s)
- Medspa Setting authorized by the Medical Director
- Health Club Setting[27] authorized by the Medical Director

All other non-ablative laser procedures shall be performed in a clean, safe environment properly equipped with universal precautions in place.

SUPERVISION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary.

All adverse reactions such as epidermal injury, pain, erythema, edema, blistering, dyschromia [hyper or hypopigmentation] textural changes [crusting or scabbing] and/or bruising shall be reported immediately to the Medical Director. Side effects may appear either at the time of treatment or shortly thereafter. Adverse reaction(s) shall be documented in the client's chart.

[27] California Business & Professions Code Section 2725 and California Code of Regulations, Section 1470-1474; Health Club Setting does not meet California performance standards. May apply in other states.

PATIENT CONDITIONS

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will not knowingly treat clients' with / on / using:

- The herpes simplex virus. In an effort to prevent a "flair up" of a client(s) condition, treatment to the upper lip, chin, lower cheeks or bikini line should be avoided. The risk of complication(s) may be reduced if prescribed antiviral medication [i.e. Zovirax or Famvir] are taken for several days prior to and after each treatment.

- A tan from sun exposure, tanning booth, self -tanning preparations. Client(s) who have a tan shall be instructed to refrain from sun and return for treatment when the tan is gone.

- Atypical moles or malignancy, pigmented lesions, tattoos [including permanent cosmetic tattoos], or vascular lesions in the treated area.

- Isotrentinoin [commonly referred as Accutane®] within 6-12 months.

- Photosensitive medications [i.e. Retin A, Alpha Hydroxyl or Glycolic Acid].

- Pregnancy.

- History of keloid scarring.

- Insulin-dependent Diabetes.

- Scarring or infection at treatment site.

- Pacemaker or internal defibrillator

TREATMENT CONSIDERATIONS

- **Depending upon the actual treatment, various protocols exist that are machine dependent such as the optical energies, fluency, number of passes and other considerations for treatment. The following list of other non-ablative procedures will outline general guidelines for treatment.**
- **Please refer to manufacturer white papers, peer to peer cite review, or other protocols that may be obtained concerning the actual condition and treatment parameters for your device.**

OVERALL RECOMMENDATIONS FOR OTHER NON-ABLATIVE LASER OR LIGHT ENERGY TREATMENTS

- Repetition rate should be established at the discretion of the operator or in relation to the patient's heat sensitivity.

- For the most pleasant treatment, always be prepared with an ice pack for post treatment cooling.

- Avoid treating any areas that exhibit sunburn, irritation, tattoos, raised lesions unless a qualified physician or dermatologist has check them.

- Patients who are using topical Retin-A should wait (2) days before treatment. Patients using Accutane type products should discontinue the medication (6) months prior to treatment.

- Do not treat directly over a site that has received a dermal filler (HA) injection within the previous (3) weeks without first getting clearance from the dermal filler manufacturer.

- With a white eye liner pencil, it can be helpful to draw a grid over the treatment area for better guidance.

- For skin types IV through VI, test spots should always be done before treatment if protocol will involve laser fluences above 20 J/cm2. Wait five to ten minutes for skin to react. Tanned or dark skin may take longer.

- Do not treat within periorbital area as deep penetrating laser energies can damage eye structures.

Note: Each skin type has its own threshold fluence at which pigmentation changes occur. To minimize hypo or hyperpigmentation, lower fluences should be used. Single pulsing is recommended, double and triple pulsing can increase the incidence of pigment changes. If hypo or hyperpigmentation occurs it is usually transient.

ACNE TREATMENTS

Overview:

Patients need to be informed that clearance of acne typically takes up to (4) treatments in order to see a good result. Acne is caused when pores or hair follicles become clogged and then infected by p. acnes bacteria. Laser light energies heat the affected area to effectively kill p. acnes bacteria and are also used in helping to shrink sebaceous glands causing them to produce less oil, limit future outbreaks and reduce pore size. Some patient's condition may become worse before it gets better which should subside as the treatments progress.

Some patients will not respond as well as others due to varying factors. Patients who are sunburned should wait until the burn subsides. Herpes Simplex, Labialis (fever blisters) can be activated by laser light energy treatments, patients can be started on antiviral medication before treatment.

Recommendations:

1. The mechanism of action for acne is bulk heating of the sebaceous glands in the treatment area which destroys the p. acnes bacteria and slows sebum output to help clear any blocked pores. The laser energy also helps to reduce any inflammation or swelling. Expect to spend approximately 3 minutes on each facial quadrant.

2. The treatment of acne can be performed in (2) ways: one is to treat the entire affected area of the face and help prevent future outbreaks. Another method is to solely treat the active lesions which can be seen at the time of treatment.

3. There is a risk of not growing beard after facial treatments or patchy hair in treated areas particularly in men with facial hair.

Note:

Depending upon your system configuration and manufacturer of the light energy device it will be necessary to acquire protocols from the manufacturer as they are different. Multiple handpieces may also be necessary to be able to perform this procedure to reduce the bacterial load associated with inflammatory acne and to reduce the sebaceous glands which require bulk heating of deeper tissues.

MELASMA TREATMENTS

Overview:

Some patients will not respond as well as others due to varying factors. Melasma tends to darken after the first or subsequent treatments. Key factors in terms of treatment response are whether there is a sufficient melanin in the affected area, the depth of the melisma, and other factors. Regardless of the treatment response, recurrence is common and can be caused by factors such as sun exposure, genetic disposition, and hormonal influences. It is important to understand that melisma, like eczema and psoriasis, may be portrayed as a chronic condition that can be controlled rather than cured with the use of laser light energies.

Recommendations:

1. Consider microdermabrasion to facilitate greater energy penetration prior to the treatment as most protocols use lower energy settings.

2. The laser is treating the condition, not the underlying systemic cause. Therefore, future recurrence is a distinct possibility.

3. Consider putting patients on a bleaching agent (hydroquinone or kojic acid) for two weeks prior to treatment.

Note:
Depending upon your system configuration and manufacturer of the light energy device it will be necessary to acquire protocols from the manufacturer as they are different. Multiple treatments may also be necessary to be able to perform this procedure to reduce the pigmentation associated with melasma. There are a number of laser light energy devices to treat melisma so the specific protocols will be different including joules of energy, fluency, and frequency of treatments.

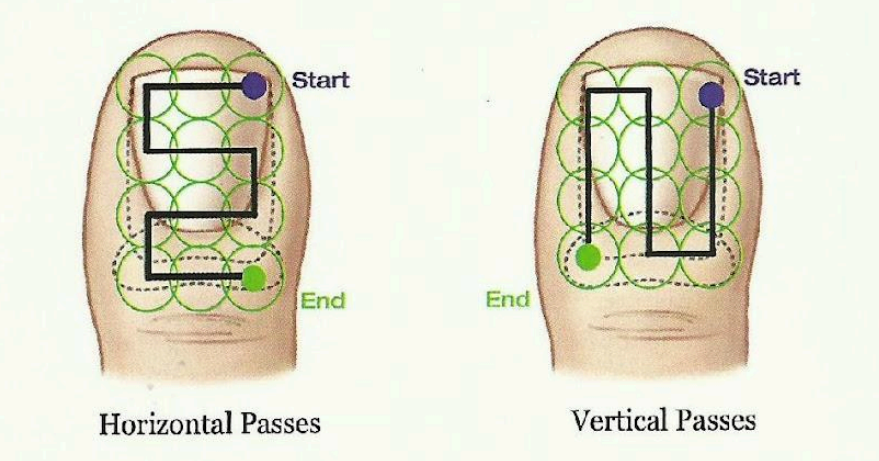
ONYCHOMYCOSIS TREATMENTS

Overview:

Some patients will not respond as well as others depending on the severity of the condition and how well the patient adheres to the recommended after treatment care. While some patients may no longer be infected, their nail may not return to its natural color. Reinfection rate can be high, especially in elderly patients and continuous foot care and monitoring their feet is the best regiment to deter reinfection.

Recommendations:

1. Typically, only a 1064ND Yag is used for the treatment of onychomycosis, each pass of the laser involves a series of slightly overlapping laser pulses applied to each nail as well as the adjacent skin, in such a way to ensure the entire nail area is treated; be sure to carry each pass through to the skin tissue immediately surrounding the nail including the nail matrix area.



2. Keep the laser beam perpendicular to the nail surface for maximum penetration and efficacy.

3. The use of medical smoke evacuation equipment should be used to remove any plume that may arise from the nail. Cooling of nails prior and after treatment may make treatment more comfortable.

Additional Recommendations:

1. Clip, debride and clean all affected nails. Fully remove any nail polish. Wait until the skin and nail fully dry before proceeding.

2. Establish the appropriate energy settings and repetition rate.

3. Make one pass of overlapping pulses completely covering the nails in a horizontal pattern. Then make one pass completely covering the nails in a vertical pattern.

4. Make additional passes on the matrix of the nail where fungus has entered the matrix. Fluence should be set as tolerated by patient.

Note:

Depending upon your system configuration and manufacturer of the light energy device (1064ND Yag) it will be necessary to acquire protocols from the manufacturer as they are different. Multiple treatments may also be necessary to be able to perform this procedure to reduce the fungal infection associated with onychomycosis.

PSORIASIS

Overview:

Some patients will not respond as well as others depending on the severity of the condition and other factors. Psoriasis lesions tend to subside after the first or subsequent treatments. Regardless of the treatment response, recurrence is common and can be caused by a number of lifestyle factors. It is important to understand that psoriasis is a chronic condition that can only be controlled rather than cured.

Recommendations:

1. Apply passes of light energy in a painting motion canvassing the entire area.

2. Use higher energy settings on thick, whitish plaque and lower energy settings on darker reddish sections.

    a. The targeted tissue may or may not exhibit a change in appearance after the first treatment.

3. Do not treat facial areas on skin types IV-VI due to the high risk of spot hypopigmentation.

4. The laser light energies is treating the condition, not the underlying systemic cause. Therefore, future recurrence is a distinct possibility.

5. Psoriasis varies widely in characteristics, no single protocol for all cases. Number of sessions vary and are considered to be as needed.

Note:
Depending upon your system configuration and manufacturer of the light energy device it will be necessary to acquire protocols from the manufacturer as they are different. Multiple treatments may also be necessary to be able to perform this procedure to reduce the pigmentation associated with psoriasis. There are a number of laser light energy devices to treat psoriasis so the specific protocols will be different including joules of energy, fluency, and frequency of treatments.

SCAR REVISION

Overview:

Some patients will not respond as well as others depending on the severity of the condition and other factors. Typically newer scars respond better than older ones due to the increased vascularity or melanin present within the scar. While collagen will be remodeled to help with skin texture, it is important to let the patient know that laser light energies will only diminish any melanin or vasculature within the scar, but will not remove the scar as an ablative laser may.

Recommendations:

1. Scars vary widely in their characteristics so there is no single protocol for all scars. Titration of laser energies is important as it will be necessary to increase the energy mode as brown/red pigmentation in the scar decreases after the initial treatment.

2. Determine the density of red or brown pigmentation in order to establish the appropriate fluence for the current treatment. Darker pigments require lower energy settings and vice versa.

3. Laser light energies can be used to treat keloid scars, but there is a risk of aggravating them. **DO NOT** treat keloid scars without an in-depth consultation with the manufacturer or advanced practitioner.

4. Use higher energy settings on thick, whitish plaque and lower energy settings on darker reddish sections.

Note:
Depending upon your system configuration and manufacturer of the light energy device it will be necessary to acquire protocols from the manufacturer as they are different. Multiple treatments may also be necessary to be able to perform this procedure to reduce the pigmentation associated with various types of scars. There are a number of laser light energy devices to treat psoriasis so the specific protocols will be different including joules of energy, fluency, and frequency of treatments.

WARTS & SKIN TAGS

Overview:

Some patients will not respond as well as others and the number of treatments for each lesion may depend on the depth and size of the underlying structure and vessel formation.

Recommendations:

1. Debriding of warts (thickened warts) is recommended for deeper energy penetration.

2. Higher fluences may be needed for plantar or resistant warts. Apply the laser energies to the lesion but also the peripheral skin tissue surrounding the lesion.

3. If the lesion persists after 3-4 treatments, you will need to increase (titrate) the energies.

Note:
Depending upon your system configuration and manufacturer of the light energy device it will be necessary to acquire protocols from the manufacturer as they are different. Multiple treatments may also be necessary to be able to perform this procedure to eliminate warts and skin tags as well as the structures underneath supporting these lesions. There are a number of laser light energy devices to treat psoriasis so the specific protocols will be different including joules of energy, fluency, and frequency of treatments.

WOUND HEALING

Overview:

Some patients will not respond as well as others for a variety of underlying reasons. Wound healing is a slow process that can take a number of treatments to visibly see results and closure, which will also depend on the severity, depth, and size of the wound as well as the patient's immune system's ability to heal. Each person's healing process, known as the healing cascade, is different and the time for this process can be very different between patients, but laser therapy can help speed these processes.

Recommendations:

1. Treatments may typically be performed once or twice weekly, for 3 weeks or more depending upon manufacturer recommendations. Treatment should be carried through to the healthy peripheral skin surrounding the wound.

2. Laser treatments do not replace traditional wound care; existing treatments should still be used together with laser treatment.

3. After the treatment, the wound should be covered with an appropriate dressing.

Note:
Depending upon your system configuration and manufacturer of the light energy device it will be necessary to acquire protocols from the manufacturer as they are different. Multiple treatments may also be necessary to be able to perform this procedure to improve the healing process and for overall wound care management. There are a number of laser light energy devices to treat psoriasis so the specific protocols will be different including joules of energy, fluency, and frequency of treatments.

Insert manufacturer protocol here including laser settings for the various Fitzpatrick skin types as well as any special considerations by the manufacturer for the machine to be utilized.

SAFETY PROCEDURES

A well-trained staff primarily assures patient safety. In an effort to protect both the operator and client, the following safety measures[28] shall be observed:

- Corneal shields shall be placed on client's eyes prior to the procedure.
- Protective eyewear shall be available at all entrances to treatment room(s). Anyone wishing to enter a treatment room during a procedure shall knock appropriately and don protective eyewear prior to opening the door.
- Personnel shall at all times [while a laser procedure is in progress] ensure that everyone present in a laser-room has protective eyewear in place.
- Treatment room(s) shall be clearly marked with appropriate signs indicating the use of lasers.
- All windows shall be covered. Never permit reflective objects such as jewelry, watches, surgical instruments or mirrors to intercept the laser.
- Wet towels shall be kept in the treatment room in case of a fire.

RECORD KEEPING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall be responsible for maintaining client records, including but not limited to client assessment, signed informed consent of risks, benefits, and potential adverse effects, number of treatments, and the client response to treatment including the quality of skin, pigmentation changes.

[28] OSHA [Occupational Safety & Health Administration] Publication 8-1.7 Guidelines for Laser Safety and Hazard Assessment.

REQUIREMENTS FOR REGISTERED NURSE

TRAINING / EDUCATION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall receive specialized training [and be certified] in the administration of Laser Hair Removal. A Medical Doctor, Doctor of Osteopath, Advanced Registered Nurse Practitioner experienced in this procedure, or a teaching institution specializing in this procedure, may perform this training and certification. Competencies to successfully demonstrate shall include:

- Mechanism of Action for the laser modality to be performed.
- Preparation of the skin
- Safety, efficacy, and complication issues
- Assessment and identification of areas to be treated
- Safe application of laser light energies [minimum 8-hours hands on training or advanced training from manufacturer]

NOTE: Other Non-FDA applications of light energies may only be performed by a physician, physician assistant and/or registered nurse[29]. Unlicensed personnel, including medical assistants may not perform any type of alternative laser procedures.[30]

[29] Business & Professions Code, Section 2725(b)(4), (c) provides the statutory authority for registered nurses to perform medical functions pursuant to standardized procedures.

[30] California Business & Professions Code, Section(s) 2069-2071 and Title 16 California Code of Regulations, Section(s) 1366-1366.4.
Use of Lasers, Dermabrators, Botox and Other Treatments by Non-Physicians, Medical Board of California Action Report, page 6, October 2012.

COMPETENCIES and DOCUMENTATION

The Medical Director and/or [applicable licensure], shall

- Document [on the appropriate form] the initial evaluation and final determination recording satisfactory completion of training and competence.

- Evaluate the competence of the Registered Nurse [RN], Physician Assistant or licensed medical personnel on an annual basis and/or as needed if indicated by client dissatisfaction or efficacy issues.

- The evaluation shall be maintained in the personnel file of the Registered Nurse [RN], Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].

DEVELOPMENT & APPROVAL OF STANDARDIZED PROCEDURE

The Standardized Procedure and Protocol for the Administration of non-ablative laser procedures has been developed jointly by the Medical Director, Administrator, and the Registered Nurse. This protocol shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

_____ _____
Nurse Date

_____ _____
Medical Director Date

_____ _____
Administrator Date

PERSONNEL AUTHORIZED TO PERFORM PROCEDURE

NAME	DATE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____

LASER OR LIGHT ENERGY MEDICAL DEVICE SAFETY POLICY

OTHER CLINICAL POLICIES AND PROCEDURES

- Laser Certification / Credentialing for Laser Privileges
- Laser Qualified Personnel
- Laser Operator Performance Criteria
- Laser Safety Operator Guidelines
- Laser Precautions
- Laser Safety Equipment
- Laser Safety Environmental Considerations
- Laser Fire Safety
- NO SMOKING Policy
- Fire Prevention
- Fire Fighting Equipment

SECTION 11

Laser Certification

POLICY:
This facility will assure that the clinical use of lasers is performed safely by the physicians or medical director and that any authorized licensed healthcare professional are laser certified for the device.

PROCEDURE:

- Physicians or authorized licensed healthcare professional must be approved by the appropriate state governing agencies concerning licensure. This approval must be specific to the type and classification of the laser being used.
- During a laser procedure the physician or authorized licensed healthcare professional has the responsibility for selecting wattage and the appropriate lens or fluency for the procedure.
- The operative permit (if applicable) states that the laser unit may be used during the aesthetic procedures.
- A current list of physicians or authorized licensed healthcare professional certified to use the laser is available in the physician credentialing file.

Credentialing for Laser Privileges

POLICY:
To ensure a high quality of care for all patients undergoing either ablative or non-ablative laser procedure by requiring educational documentation for laser training.

PROCEDURE:

- Physicians or authorized licensed healthcare professional attends a comprehensive laser workshop or equivalent for the laser specified and to be utilized within the facility.
- The workshop or equivalent includes intense didactic and hands-on training.
- Physicians or authorized licensed healthcare professional may do preceptorship training with an experienced laser physician as part of his/her training including manufacturer training.
- Copies of all laser certificates are kept in the physician's credentialing file.
- All laser procedures and techniques are to be FDA approved or appropriate standard of care guidelines and must follow community standards.

Laser Qualified Personnel

POLICY:
The facility assures the safe use of lasers by assigning only qualified personnel to operate the laser equipment.

PROCEDURE:
Personnel operating laser equipment are provided with comprehensive in-service instruction before being assigned to laser procedures. A written record of in-service completion is retained on all qualified personnel.

Laser Operator Performance Criteria

- Employee has all laser Policies and Procedures
- Has attended equipment in-service by the Laser Safety Officer
- Follows safety precautions while setting up the room for the procedure and possible assembly of the equipment.
- Knows how to assemble the laser with the delivery systems (i.e. hand piece, micromanipulator, and operative laparoscope)
- Test fires equipment before use.
- Operates Control panel properly:
    - Power Setting
    - Standby/Ready mode
    - Emergency Off
- Assembles, operates, and monitors plume evacuation equipment (if necessary)
- Completes all documentation forms.
- Knows proper methods of cleaning and storing of lasers and accessory equipment.
- Demonstrates ability to monitor a laser safe environment.

Laser Safety Personnel / Operators

POLICY:

The facility's Laser Safety Operators (if applicable) are responsible for the safe operation of the laser though all employees are trained in laser safety.

PROCEDURE:

- Authorized personnel trained in laser safety or Laser Safety Nurse (if applicable) are always present while the laser is operated during a procedure, and will operate the control panel. Only authorized personnel trained in laser safety are responsible for the key used or codes needed to turn the laser on and off.
- When the laser is not in use, it must be placed in "standby" mode or the key is pulled from the device.
- Authorized personnel trained in laser safety and operating the device are responsible for:
    - Transporting the laser and accessories needed
    - All laser documentation
    - Placing laser warning signs on access doors, providing and ensuring the use of protective eye wear for patients and other staff during the laser procedure.
    - The proper storage of lasers, laser equipment, and supplies.
    - Ordering laser supplies (if applicable) and maintaining inventory.
    - All laser photography unless otherwise delegated to others.
    - Actively helping in training other qualified licensed healthcare professionals as assigned.
- Maintaining a laser log in which the following information will be recorded:
    - A stamped patient label or similar containing all patient information.
    - Laser operator or physician performing the laser treatment.
    - The type of procedure / pre-op DX
    - The wattage or joules of energy used.
    - Mode
    - Time of procedure.

Laser Safety Equipment

POLICY:

This facility provides proper safety equipment for use with medical laser equipment, and requires its use by staff and patients.

PROCEDURE:

- By definition, a class IV laser or any IPL device could cause eye injury either by direct contact with beam and laser light energies or by reflection of the beam on a shiny surface.
- All persons in the treatment room or area are provided with safety glasses and must wear them at all times when the laser is in use.
- Laser procedures are at times performed under general or local anesthesia, the patient's eyes are protected with gauze pads moistened with sterile saline and appropriate laser protective eyewear (cups, glasses, goggles), as required.
- For Ablative Laser Procedures (CO2, Erbium Yag, YSGG):
    - Eyewear with appropriate wave length/optical density should be worn.
    - Side shields are recommended for laser team members in close proximity to the laser tissue interaction site.
    - Prescription glasses are not considered appropriate eye protection.
    - Contact lenses are not considered appropriate eye protection.
- Protective eyewear must be inspected periodically; any scratched lens surface allows laser beam transmission that could harm the wearer's eyes.
- To prevent reflection of the laser light energies, special precautions should be followed. Instrumentation that is not dulled or ebonized should be covered with towels and moistened with sterile saline to decrease reflection.
- Anodized or Dulled Instrumentation;
    - Instruments can be anodized or dulled to decrease laser light energies which reduce the risk of potential eye or fire damage. Instruments shouldn't be etched, as surface will be disrupted and allow reflection.
    - Tooth guards can be used to decrease the chance of inadvertent laser energy damage to teeth, either by direct or reflective contact. The tooth guard should be tested before laser surgery to make sure it can withstand the impact.
    - Glass instrumentation has the potential of shattering, Metal rods should not be used due to the absorption of heat energies and the potential of damage to tissue. Plastic instrumentation should not be used as they may melt or burn when interacting with laser energies.
- Masks and gloves should be worn by anyone in close proximity to tissue interaction site.

Laser Safety Environmental Considerations

POLICY:

This facility provides a safe environment for staff and patients in which to operate medical laser equipment.

PROCEDURE:

- Warning signs are placed on all doors leading into the procedure area where the laser light energy device or laser is being used. Appropriate protective eyewear is available at the entry door.
- All laser type devices are to be turned off when light energy transmission is not required. When these devices are left unattended for a substantial time, such as during lunch, overnight, or at shift change, the device is turned off and the key returned (if applicable) to the assigned place for safe keeping. The laser light energy device or laser is turned to “standby” during a procedure when transmission is not required.
- Any laser type device or laser is not to leave the premises or procedure room or the assigned designated area without permission from authorized personnel.
- A pre, intra, and post-operative safety check is done before operating the procedure, many newer lasers are self-calibrating but for other devices a pre, intra, and post-operative safety check may be required.
- If the laser type device or laser use keys for the turning on and off of the machine, keys are available only to persons authorized to operate devices.
- No flammable prep solutions shall be used in the presence or laser or laser type devices.
- Windows (if applicable) must be covered properly depending upon the type of laser or device used.
- Foot Pedal Placement
    - Any foot pedal is identified verbally by personnel placing the pedal on the floor.
    - The foot pedal will be placed on the floor for use by the operating physician or authorized personnel, and should not be operated by other non-authorized staff members.
    - All foot pedal electrical wiring is inspected routinely for fraying or breaks to the connectors or device.

Laser Fire Safety

This facility provides and follows guidelines that reduce the hazard of a laser induced fire.

PROCEDURE:

- By definition, a class IV laser presents a fire hazard whether by its direct beam or by its reflection.
- Both cloth and paper drapes are flammable. To decrease the chance of fire, wet draping materials can be used in areas that are close to the laser interaction site that could possibly be ignited by direct or indirect laser beam impact.
- Saline, water, or appropriate fire extinguishing equipment must be readily available in case of fire.

No Smoking Policy

It is the policy of this facility that NO SMOKING will be allowed in the building at any time. This shall be reinforced with signs and notices in the Center stating this policy. Smoking will be allowed outside the building.

Should staff members wish to smoke, they must do outside the building during assigned break times. In the clinical areas, if a staff member wishes to leave the building to smoke, they must wear a lab coat which is buttoned. Shoe covers worn outside (if applicable) must be changed prior to re-entering the clinical area.

Ashtrays of non-combustible material and safe design shall be provided in all areas where smoking is permitted.

Smoking is prohibited in any room where flammable liquids, combustible gases, or oxygen are used and/or stored, or in any other hazardous location. Such areas will display a “no smoking” sign.

Fire Prevention

Fire extinguishers are maintained and inspected annually. Fire extinguishers are inspected visually on a quarterly basis for secure wall mounting, inspection tags, adequate pressure, and possible tampering or damage.

"NO SMOKING" are posted within the facility. Smoking is not permitted within the facility for the health of staff patients and visitors.

No explosive agents will be used at the facility.

Fire-Fighting Equipment

The following fire-fighting equipment is available at the facility:

- Fire Extinguishers:
  - Fire extinguishers are located throughout the building.
  - The only type fire extinguisher in use at the facility is the ABC multipurpose dry chemical extinguisher.
  - Each extinguisher must bear a tag stating date of service and name of person performing service.
  - The ABC extinguisher is safe to use on any type of fire.
    - Class A – Wood, cloth, paper, rubbish, and other ordinary combustibles.
    - Class B – Flammable liquids such as oil, gasoline, paint, or grease.
    - Class C – Electrical such as burning motors, controls or wiring.
  - How to use the fire extinguishers:
    - Carry extinguisher by the handle on top, holding it erect.
    - Pull out metal pin from side of handle to unlock.
    - Raise horn (nozzle), or hose, and point to base of fire.
    - Squeeze valve grip handle to open valve, contents will be discharged.
    - Direct discharge at base of flames from side to side, approx. 6 feet away.
    - To cool substance and prevent possible re-flash, continue discharge even after fire disappears.
- Wet Blankets:
  - May be used to smother a small fire. Should fire occur in a wastebasket, place a wet pillow (if possible) into the basket to smother fire.
- Fire Alarm System (If Applicable)
  - Pulling down the handle will activate the fire alarm.
- Water:
  - Do not use water on electrical fires such as burning motors, controls, and wiring, or on flammable liquids such as oil, gasoline, paint, or grease.
  - Water is excellent for extinguishing oxygen-type related fires.

POLICIES AND PROTOCOLS FOR TOPICAL ANESTHESIA

The RN, PA or licensed medical personnel will:

1) Not apply cream to large areas of denuded or inflamed skin which could lead to excessive systemic absorption.
2) Not apply cream to patients with a history of allergic reactions to benzocaine, tetracaine or lidocaine.
3) Not apply cream to patients taking Class I antiarrhythmic drugs
4) Not apply cream to patients who give a history of congenital or idiopathic methemoglobinemia
5) Not apply cream to patients who give a history of severe hepatic disease
6) Remove makeup, using a cleanser suitable for the skin type.
7) Degrease the skin [optional].
8) Thoroughly dry the skin with clean gauze.
9) Apply a thin film of cream to the area which will be treated, using a cotton applicator on tongue depressor. The patient can be allowed to apply the cream. The patient should be advised to use an applicator and not use uncovered digits which will become numb.
10) Wait for 10-20 minutes for the cream to work.
11) Wipe off excess cream prior to treatment.
12) Advise the patient that numbness will persist for up to 3 hours and that he/she should avoid inadvertent trauma to the treated area by scratching, rubbing, or exposure to extreme hot or cold temperatures until complete sensation has returned.

PRESCRIBING FORMULARY

The following drugs are authorized by the supervising physician's prescription to be used by the Physician Assistant in accordance with Sections 4047.5, 4048, and 4228 of the Business and Professions Code.

1) Botox Cosmetic™, Xeomin™, and Dysport™ to be administered as per protocol and manufacturer recommendations for dosage and constitution.
2) Sotradecol™ and Asclera (POL)™ to be administered as per protocol and manufacturer recommendations.
3) Topical anesthesia cream to be administered as per protocol.

GENERAL HEALTH QUESTIONNAIRE

Client Information

Name _____ E-Mail Address _____

Address _____ City _____ ___ State _____ Zip _____

Home Phone _____ Work Phone _____ Fax _____

Medical Information

Date of Birth ___/___/___ Age ____ Family Physician _____

Phone _____

Do you smoke? ____ How often? _____ _Do you drink alcohol? ____ How often? _____

Have you ever been treated for: [please circle]

Acne Depression Skin Disease High Blood Pressure Cold Sores Diabetes Cancer Sinus

List all medications you are currently taking (especially Accutane (Isotretinoin) or any photosensitizing drugs):

_____

Are you pregnant? _____ Are you on Hormone therapy / Birth Control? _____

Do you wear contact lenses? _____

List any medications you are allergic to: (latex) _____

Do you have or have you had: [please circle]

Heart problems Herpes Keloidal scarring Cold sores Pacemakers Cancer/Melanoma

Explain _____

Any photosensitive disorder? (lupus, porphyria, sun rash, etc.) _____

Past medical problems: _____

Personal Information

Have you had cosmetic surgery? _____

How do you want to improve your skin? _____

What previous skin care treatments have you had? _____

What skin care are you currently using? _____

Sun History and Lifestyle

Do you work inside or outside? _____

Do you use chemical sun tanning lotions? Y N If yes, when did you last use them _____

When was your last sun exposure? _____ Do you use tanning beds? _____

Are your hobbies done mostly inside or outside? _____

When exposed to the sun without protection for about 1 hour, how does your skin react?

Burns always, never tans □ Burns sometimes, sometimes tans □

Burns always, something tans □ Tans always □

Ethnic Background: Caucasian Hispanic Asian Mediterranean Middle Eastern African American

Please check all treatments/services that interest you:

___ Professional skin care - Botox® ___ Microdermabrasion ___ Lasers ___ Fillers

___ Sclerotherapy (Leg Veins) ___ Micro-Needling ___ PRP ___ Other

How did you hear about our services? _____

Patient Signature _____ Date _____

GENERAL MEDSPA PROCEDURES

CLINICAL PROTOCOLS

During training, your staff will be given a comprehensive set of Clinical Policies & Procedures. As a licensee, familiarization with these "guidelines" will assist you in the effective operation of your Med Spa Business.

Note: It is incumbent upon Med Spa licensee(s) and their staff to ensure the policies and procedures are current, valid and understood by essential personnel. Knowledge and the ability to articulate the regulations to properly operate a Med Spa, will expedite and assist in an audit by a duly authorized regulatory agency.

In a recent inspection of a Med Spa facility by the California Department of Consumer Affairs, some of the questions and requests for documentation have included:

- Who owns this facility?
- Where is the physician?
- We would like to review your clinical protocols. In the protocols, the name(s) of anyone performing procedures must be listed – full and part time.
- If you use photos in your advertising, was it a model or patient? [Looking for deceptive advertising claims.]
- Has your physician and read and signed the policies and procedures [protocols]?

Federal regulations governing specific operations of selected procedures are applied equally. However, licensee(s) will discover individual state regulations[31] will vary with wide latitude. It is strongly recommended to have lead and supervisory personnel review the policies and procedures contained herein. Amendments, modifications, and any proposed changes should be made prior to opening of your facility.

In addition, the Medical Director [of your respective Med Spa] shall review the policies and procedures and affirm to a statement that these guidelines are performed under his/her supervision.

MEDICAL HISTORY

The Policies & Procedures Manual includes a medical history form. This type of record is completed by dentists', physicians' and other healthcare professionals. It is familiar to the general population, since almost everyone has completed one at one time in their life.

The medical history form [like the consent form] is to be completed and signed by the patient. The Registered Nurse [RN] should review the medical history form [for

[31] As an example, regulations in California are generally more extensive than in most of the contiguous states.

completeness] prior to it becoming a permanent record. Most states allow the RN or the Nurse Practitioner [NP] to assist in the preparation of this form. Exceptions to this practice will be noted in the appropriate locations of the Policies & Procedures Manual.

The Forms Manual contains sample forms for: Patient Skincare Consultation, Patient Medical and Cosmetic History Information, Laser Hair Removal Assessment and Laser Hair Removal Treatment Record.

PHYSICAL EXAMS

Several states [such as California] require by regulation[32] a physician to perform a 'good faith' physical exam before a prescription for Botox® may be written. The laser procedure(s) require only a medical screening and the appropriate form(s) be completed before their application may be administered.

In states governed by this regulation, the licensee may elect to group patients [who need an exam] into appointments that best fit the schedule of their respective Medical Director.

Other options may include:

1. The Medical Director may have these types of patient(s) visit his/her primary office [if other than the Med Spa] for a no-appointment, on-the-spot exam[33], or

1. The Medical Director may employ a resident physician [paid on an hourly basis] to provide the exams during extended hours or on weekends. Your HWI Business Development contact will assist you in making the most appropriate staffing decision to accomplish this task.

MEDICAL RECORDS

A section dealing with Medical Records is contained in the Policies & Procedures Manual. Record(s) must contain sufficient information to identify the patient, justify the [selected] procedure/treatment and assure the patient history was properly developed. In addition,

[32] Business & Profession Code 2242 – The Medical Doctor must provide a good faith examination of the patient before providing a Botox® prescription. To prescribe without a good faith examination is unprofessional conduct and may be grounds for disciplinary action by the Medical Board of California against the physician's license.

[33] Exam cost should be borne by the Med Spa.

information delineating patient knowledge of associated risks will be documented [Informed Consent Form] within the medical record.

A patient 'chart' will be initiated for each individual(s) and should contain all related forms. Patient information [name, address and telephone numbers] may also be input into Med Spa [business] computers.

The following guidelines are recommended to secure and maintain medical record information:

- Medical records shall be kept 'Confidential.'
- Records may only be released upon the completion of a 'Release of Information' form by the patient.
- Records should be kept in a locked file cabinet and accessible only to authorized staff members.
- Release of medical information and/or removal of medical records are governed by Federal and state regulations. Original records should always remain at the treating facility.
- Electronic data[34] recording may be used within the Med Spa and is considered a 'draft' until a hard-copy printout is made part of the permanent medical record.

The Medical Director shall ensure that the Med Spa staff is properly trained to gather and secure within a patient(s) file the following:

- Information or Referral [Face] Sheet
- Medical History
- Signed Consent Form(s)
- Physicians' prescription(s) [if applicable]
- Copy of any pertinent physical examination, and
- Chronological narrative [notes] containing nature of visit, date, time should be signed or initialed by staff member obtaining information

RECORD RETENTION

Med Spa Licensee(s) should receive from their respective insurers, definitive information regarding the length of time that medical records should be retained. Standard practice is to retain medical records a minimum of seven years for adults [over 18 years of age] from the date the patient undergoes a procedure. For patients under 18 years of age, records should be kept for a period of **three** years past their 18th birthday or seven years after discharge, whichever is longer.

[34] Fact Sheet - National Standards for Transactions, Security and Privacy; U.S. Department of Health & Human Services, March 3, 2003[copy provided at the end of this manual].

Note: Given the litigious nature of our society, prudence would dictate the retention of medical records **indefinitely**! In the event a licensee and their respective Med Spa facility cease to conduct business, medical records must be stored [locked and safeguarded] at an appropriate location for the prescribed time period.

A good business practice to follow is to develop a schedule where a periodic review of records is initiated and retention dates are duly noted [either manually or electronically]. This review should include patient's charts or medical records, monthly income and expense summaries, tax records, etc.

ADMITTING & PATIENT CONSENT

Med Spa staff shall be trained in the proper method of admitting to include completion of the Informed Consent Form. 'Admitting & Consent' are an integral step of the screening process. During the initial consultation or contact with a prospective patient, the Med Spa employee shall ensure the patient "**clearly**" understands what they [the patient] are about to undergo. The Informed Consent Form is the vehicle to facilitate that action.

Informed Consent asks general questions such as: Name, address and other personal descriptors. Also included are general medical questions that are specific to the type of procedure the patient is seeking. It advises the patient on the potential benefits as well as associated complications and risks. The Consent Form becomes a permanent document of the patient's medical record.

Some phrases and words Med Spa employee(s) should key upon on the Informed Consent Form(s) are as follows:

- Consent to type of procedure,[i.e. Botox®, etc.]
- It has been explained to me that there are certain inherent and potential risks and side effects in any [invasive] procedure and in this specific instance such risks include but are not limited to…
- I am aware that when…
- I hereby voluntarily consent to treatment with…
- The procedure has been explained to me. I have read the above and understand it. My questions have been answered satisfactorily. I accept the risks and complications of the procedure.
- Signature

Note: Patient(s) who schedule multiple appointments for a series of [similar] treatments [i.e. Laser Hair Removal generally requires three treatments over a period of four to six weeks] shall be required to **sign only one** Informed Consent Form. A patient who elects to undergo **another type of procedure** [i.e. Microdermabrasion, Botox®, etc.] **must sign a separate** Informed Consent Form **for each procedure selected!**

Finally, some Med Spas opt to publish separate information sheets on Pre & Post Treatment Instruction(s) with associated expectations. Exemplars of these forms are included in your manual.

Note: Pre and Post Treatment Instructions are an important document for the RN to review with the patient, however, this form is not signed by the patient nor is it required to be retained as part of the permanent medical record.

REFUSAL TO TREAT PATIENT(S)

A large percentage of potential elective and/or cosmetic patient(s) have very high [but sometimes unrealistic] expectation(s) regarding the outcome or result of their treatment(s). In an effort to minimize patient complaints or grievances Med Spa employee(s) should be thoroughly trained to screen potential patients.

Secondary to this training, is empowering the Med Spa employee with the requisite authority to decline [refuse] treatment to *any patient* who would:

- be categorized as marginal for the procedure elected, or
- indicate that the general "results" [no matter how perfect] the patient would remain unsatisfied.

Each of the elected procedures [in this P&P Manual] has a guideline or selection criteria that the RN should follow in making a determination of the patient(s) suitability to have the procedure. Some of the reasons to decline a patient include [but are not limited to]:

- Condition of skin, pigmentation [color] or hair
- Patient(s) unrealistic expectation of result(s) by having fewer that the recommended number of treatments
- Patient has received treatment somewhere else with unsatisfactory results
- Patient is unwilling to comply with pre or post treatment instructions
- Procedure is clinically contraindicated i.e., taking photo rejuvenation drugs, diabetes, pregnancy or history of keloid scarring

Note: Patients with a pacemaker, on blood thinning medication or having a cardiac history **may** have a procedure **if** they get written clearance from their treating cardiologist.

INCIDENT(S) GENERATING COMPLAINTS

The Med Spa licensee needs to distinguish the difference between complaints from a patient who is disappointed in the results of a procedure, from a 'patient incident' where it is alleged that a Med Spa employee caused injury to them as a result of an elected procedure.

When it is brought to the attention of a Med Spa employee that a patient has a complaint [regardless of the nature] the employee should immediately refer the concerned patient to an authorized or designated clinician. The employee making initial contact with a 'patient concern' may receive all or part of the information regarding the incident.
Med Spa employee(s) should be admonished not to offer advice or consultation regarding the incident but to refer it to the Medical Director or on staff physician without delay.

Patient complaint(s) related to procedure results may be handled as simply as offering an additional ***free*** treatment of the same procedure or offering something of a similar nature either free or at a greatly reduced price. Here, customer satisfaction may be quickly achieved at a minimum cost.

Note: Med Spa licensee(s) [owners] should have a clear policy on this matter. Employee(s) should understand the parameters in which this policy may be implemented and select personnel given the authority to administer said policy when required.
Advice from legal counsel, CPA or tax adviser should be sought to determine how free or remedial treatments are to be documented. Generally, you may be advised to create both an invoice and a receipt.

A 'patient incident' is a more serious matter. The Policies & Procedures Manual will detail how such an incident should be handled. The Medical Director should be notified immediately. Med Spa licensee(s) / owners will want to be notified in writing at the earliest possible time following the incident by a designated employee from their clinical staff. Generally, an injured patient should be referred to a local Dermatologist or to the Medical Director of the respective Med Spa for an examination[35]. It is incumbent upon the Med Spa employee(s) to properly document any incident in the patient's medical record [chart]. A sample of an 'Occurrence Report' is in the Forms Manual.

If the incident involves a medical device [as the cause of illness, serious injury or death] it shall be reported on FDA Form 3500A (MEDWATCH). The P&P Manual will cover reporting procedures in detail.

[35] The examination should be done at no charge or cost to the patient.

Note: FDA Form 3500A shall be filed within 10 days of an incident with both the manufacturer and the United States Food and Drug Administration.

EMERGENCY MANAGEMENT

Emergency management is designed to train employee(s) in the preparation, function and response to natural disaster(s) and other emergencies [both major and minor]. The Policies & Procedures Manual will cover disaster planning in detail. **ALL** employees [regular or contractor] should be trained and participate, on an annual basis, in an emergency drill.

The Med Spa licensee / owner have a responsibility to their employees', patients' and the public. An axiom of police, fire and other first responders' states: **"If you fail to plan, then you plan to fail!"**

Emergencies may include, but are not limited to:

- Earthquake
- Fire
- Storm/Flood
- Hazardous Materials Spill
- Tornados
- Thunderstorms
- Civil Unrest
- Power Failure [outages of short or long duration]

The Med Spa emergency plan [included in the P&P Manual] will cover the handling of patients, personnel, protection of medical records and assistance to the public. Med Spa employees' should be knowledgeable in response techniques and understand their specific or assigned role in an emergency situation.

If the Medical Director or other physician is on site during an emergency then he/she will assume the role of Team Leader or Incident Commander[36]. If no physician is available, then a senior designated medical person [RN or NP] will act as the Incident Commander.

Emergency telephone [contact] information should be conspicuously posted near all installed telephones. As part of their emergency training, Med Spa employees' must clearly understand whom to notify [in priority sequence] in the event of an emergency or critical incident. Not all emergencies require or qualify for a 9-1-1 response. Med Spa facilities should have readily available alternate telephone numbers for local police, fire, poison control, etc.

[36] Nationally recognized 'Standardized Emergency Management System/Incident Command System [SEMS/ICS] designation/title. SEMS/ICS is designed to manage both emergency and non-emergency incidents for large or small occurrences. Many companies have established their own internal SEMS/ICS structure for the protection of their business and to assist with the coordination of fire and law enforcement response activity during emergency situations.

Given the noninvasive and relatively safe procedures that are offered in the Med Spa, it is unlikely that an acute medical emergency will occur. However, prudence dictates that preparation and planning for such an eventuality is undertaken. The Med Spa P&P Manual will be comprehensive in the handling of medical emergencies such as:

- Seizures
- Burns
- Fainting
- Cardiac Arrest
- Falls
- Shock
- Lacerations, minor cuts and bruises

The Med Spa facility should have a first aid kit, a resuscitation kit and possibility a 'CRASH' cart on site with employees' trained and proficient in their use. Monthly, the senior or lead clinician should check expirations dates of medical supplies, restock the first aid kit and insure all emergency equipment are in good working order. An inventory list with the inspecting person's initials should be maintained for review. Items in need of repair, recharging or restocking should be properly noted and the appropriate vendor notified in a timely manner.

Patient(s) who are injured or suffer from a medical emergency should be handled according to designated emergency protocols.

ENVIRONMENTAL CONCERNS

The Med Spa licensee / owner must maintain their facility in a sanitary manner and have in place an infection control program. The P&P Manual contains a detailed section dealing with 'Universal Precautions', infection control and sanitation.

Four of the primary environmental concerns to be discussed are:

- Washing of hands
- Disposal of medical waste
- Laundry, and
- Pest Control

At all times, while handling patient(s), Med Spa employees' should employ 'Universal Precautions' to prevent potential contamination from blood borne pathogens.
The most common and effective 'Universal Precaution' is the Washing of Hands. Med Spa employees should employ the proper technique and use an effective anti-bacterial soap to prevent the spread of infection.

The disposal of Medical Waste is closely regulated by federal[37] and state regulations. Generally a Med Spa will not generate a significant quantity of medical waste. If Botox® is a procedure offered at a specific Med Spa, then the services of a contractor, licensed to dispose of biohazardous and/or infectious waste will be required.

Bio-hazardous and/or infectious waste products may only be disposed of in special containers properly marked as designated by government regulations. This topic is covered in the P&P Manual.

Some Med Spas may elect to use linen as covers for treatment tables, employees' may wear scrubs or special uniforms and patient(s) may use towels and robes before and after treatment procedures. All of these items will require professional laundry service. An option for the Med Spa licensee / owner to consider in an effort to minimize cost and maximize efficiency is disposal linen or paper products.

In addition, Med Spa licensee(s) / owner(s) may wish to offer their employees' an annual uniform allowance which will require the employee to purchase, clean and maintain their own uniforms and eliminate one of the concerns regarding hygiene and infection control.

Finally, pest control concerns. The Med Spa facility should at all times be clean and free of rodent and/or insect infestation to the extent that is reasonably achievable. No patient, spending their hard earned money for an elected procedure, wishes to see a mouse or cockroach sharing the treatment room where they are sitting.

A good general business practice is to contract with a professional exterminator who will make regular inspections and perform pest control applications as required. Employee(s) can contribute to a clean environment by covering food in lunch rooms and keeping doors and windows closed.

EQUIPMENT MAINTENANCE

The Policies & Procedures Manual contains a written preventative maintenance program to insure the equipment is in calibration and is properly maintained consistent with the manufactures' recommendations.

Medical equipment that is straightforward and electronic calibration is visually displayed for Med Spa clinicians to check before each procedure. In addition, weekly each piece of equipment should be inspected for:

[37] A bio-hazard or infectious waste product may fall under the definition of the Department of Transportation [DOT] Title 49 Code of Federal Regulation, Division 6.2, 'Infectious Substance.' Special transportation and disposal guidelines apply if a waste product falls within the purview of this regulation.
Questions regarding waste products generated by Med Spa facilities may be obtained from the DOT at 1-800-HMR-4922 or from the DOT Website http://hazmat.dot.gov/

- Frayed cords
- Broken or worn parts
- Inaccurate meter readings
- Battery or power level(s)
- Equipment plugged into grounded electrical outlets [only]

Other electronic equipment must be calibrated yearly by a certified technician with the results stored in a designated binder if directed by the manufacturer.

AUTHORIZATION FOR AND RELEASE OF MEDICAL PHOTOGRAPHS/SLIDES/ VIDEOTAPES

Aesthetic treatments and various medical treatments are a visually oriented specialty. As such it is necessary that medical photographs be taken before, during and after a surgical procedure or treatment. Similar to other imaging techniques like x-rays or CT scans, this allows for proper planning before procedures and follow up evaluation afterward.

Photographs are required only for the body part in question. This means that unless the planned treatment is on the face or head itself, the images typically do not include the face. Consent is required to take such images. Additionally, patients may consent to release these medical photographs/slides, and videotapes for a stated purpose such as for use in instructional, educational, or promotional materials.

These materials are very important to insure continued understanding of the treatments available to all patients. Please read carefully the information contained in both sections below, and provide your consent where applicable. **A signature in section 1 is required to receive your care at [name of practice], a signature in section 2, while encouraged, is optional**.

1. CONSENT TO TAKE PHOTOGRAPHS/SLIDES/VIDEOTAPES

I hereby authorize **[physician name]**, Medical Director of **[name of practice]**, and/or his associates or licensees to take pre-procedural, and post-procedural photographs, slides, and/or videotapes.

I consent to the use of these images for the purposes of pre-procedural planning and post-procedural evaluation by **[physician name]** and/or the staff of **[name of practice]**, and I understand that they shall be made a part of my medical record.

Patient Signature: _____ Date:_____

Parent or Guardian (if patient is under 18 years of age):_____

Witness: _____

2. CONSENT FOR RELEASE OF PHOTOGRAPHS/SLIDES/VIDEOTAPES

I hereby authorize **[physician name]**, Medical Director of **[name of practice]**, and or his associates or licensees to use pre-procedural, procedural, and post-procedural photographs, slides, and/or videotapes for professional medical or promotional purposes as deemed appropriate by them including but not limited to display of these images on public or commercial television, electronic digital networks, scientific medical publications, lay publications, or during lectures to medical or lay groups for the purposes of informing the medical community or the general public about aesthetic or medical treatment procedures available at **[name of practice]**. Neither I nor any member of my family will be identified by name at any time. Unless it is necessary to include it,

my face will not appear in the images. I understand that in some instances the images may portray features which could make my identity recognizable.
I understand that I will not be entitled to monetary payment or any other consideration as a result of any use of these images and I hereby grant this consent as a voluntary contribution in the interest of medical education. This permission may be rescinded by me at any time to prohibit future use by direct written communication with **[physician name] or [name of practice].**

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Patient Signature: _____ Date:_____

Parent or Guardian (if patient is under 18 years of age):

_____

Witness: _____

United States Department of
Health & Human Services

FACT SHEET

March 3, 2003

Contact: HHS Press Office
(202) 690-6343

ADMINISTRATIVE SIMPLIFICATION UNDER HIPAA:
NATIONAL STANDARDS FOR TRANSACTIONS, SECURITY AND PRIVACY

Overview: To improve the efficiency and effectiveness of the health care system, the Health Insurance Portability and Accountability Act (HIPAA) of 1996 included a series of "administrative simplification" provisions that required the Department of Health and Human Services (HHS) to adopt national standards for electronic health care transactions. By ensuring consistency throughout the industry, these national standards will make it easier for health plans, doctors, hospitals and other health care providers to process claims and other transactions electronically. The law also requires the adoption of security and privacy standards in order to protect personal health information. HHS is issuing the following major regulations:

- Electronic health care transactions (final rule issued);
- Health information privacy (final rule issued);
- Unique identifier for employers (final rule issued);
- Security requirements (final rule issued);
- Unique identifier for providers (proposed rule issued; final rule in development);
- Unique identifier for health plans (proposed rule in development); and
- Enforcement procedures (proposed rule in development).

Although the HIPAA law also called for a unique health identifier for individuals, HHS and Congress have indefinitely postponed any effort to develop such a standard.
Under HIPAA, most health plans, health care clearinghouses and health care providers who engage in certain electronic transactions have two years from the time the final regulation takes effect to implement each set of final standards. More information about the HIPAA standards is available at http://aspe.hhs.gov/admnsimp/ and http://www.cms.gov/hipaa

BACKGROUND

Today, health plans, hospitals, pharmacies, doctors and other health care entities use a wide array of systems to process and track health care bills and other information. Hospitals and doctor's offices treat patients with many different types of health insurance and must spend time and money ensuring that each claim contains the format, codes and other details required by each insurer. Similarly, health plans spend time and money to ensure their systems can handle transactions from various health care providers and clearinghouses.

Enacted in August 1996, HIPAA included a wide array of provisions designed to make health insurance more affordable and accessible. With support from health plans, hospitals and other health care businesses, Congress included provisions in HIPAA to require HHS to adopt national standards for certain electronic health care transactions, codes, identifiers and security. HIPAA also set a three-year deadline for Congress to enact comprehensive privacy legislation to protect medical records and other personal health information. When Congress did not enact such legislation by August 1999, HIPAA required HHS to issue health privacy regulations.

Security and privacy standards can promote higher quality care by assuring consumers that their personal health information will be protected from inappropriate uses and disclosures. In addition, uniform national standards will save billions of dollars each year for health care businesses by lowering the costs of developing and maintaining software and reducing the time and expense needed to handle health care transactions.

COVERED ENTITIES

In HIPAA, Congress required health plans, health care clearinghouses, and those health care providers who conduct certain financial and administrative transactions electronically (such as eligibility, referral authorizations and claims) to comply with each set of final standards. Other businesses may voluntarily comply with the standards, but the law does not require them to do so.

COMPLIANCE SCHEDULE

In general, the law requires covered entities to come into compliance with each set of standards within two years following adoption, except for small health plans, which have three years to come into compliance. For the electronic transaction rule only, Congress in 2001 enacted legislation allowing a one-year extension for most covered entities provided that they submit a plan for achieving compliance. As a result, covered entities that qualify for the extension will have until Oct. 16, 2003 to meet the electronic transaction standards instead of the original Oct. 16, 2002 deadline. (Small health plans must still meet the Oct. 16, 2003 compliance date and are not eligible for an extension under the new law.) The legislative extension does not affect the compliance dates for the health information privacy rule, which remains April 14, 2003 for most covered entities (and April 14, 2004 for small health plans).

DEVELOPING STANDARDS

Under HIPAA, HHS must adopt recognized industry standards when appropriate. HHS works with industry standard-setting groups to identify and develop consensus standards for specific requirements. For each set of standards, HHS first develops proposed requirements to obtain public feedback. After analyzing public comments, HHS makes appropriate changes before issuing a final set of standards. The law also allows HHS to propose appropriate changes to the HIPAA regulations to ensure that the standards can be implemented effectively and be maintained over time to continue to meet industry needs.

ELECTRONIC TRANSACTION STANDARDS

In August 2000, HHS issued final electronic transaction standards to streamline the processing of health care claims, reduce the volume of paperwork and provide better service for providers, insurers and patients. HHS adopted modifications to some of those standards in final regulations published on Feb. 20, 2003. Overall, the new standards establish standard data content, codes and formats for submitting electronic claims and other administrative health care transactions. By promoting the greater use of electronic transactions and the elimination of inefficient paper forms, these standards are expected to provide a net savings to the health care industry of $29.9 billion over 10 years. All health care providers will be able to use the electronic format to bill for their services, and all health plans will be required to accept these standard electronic claims, referral authorizations and other transactions.

In December 2001, Congress adopted legislation that allows most covered entities to obtain a one-year extension to comply with the standards, from Oct. 16, 2002 to Oct. 16, 2003. To qualify for the extension, the covered entity must submit a plan for achieving compliance by the new deadline. (The legislation did not change the compliance date for small health plans, which remains Oct. 16, 2003.) HHS' Centers for Medicare & Medicaid Services (CMS) issued a model compliance plan that covered entities may use to obtain an extension.

PRIVACY STANDARDS

In December 2000, HHS issued a final rule to protect the confidentiality of medical records and other personal health information. The rule limits the use and release of individually identifiable health information; gives patients the right to access their medical records; restricts most disclosure of health information to the minimum needed for the intended purpose; and establishes safeguards and restrictions regarding disclosure of records for certain public responsibilities, such as public health, research and law enforcement. Improper uses or disclosures under the rule are subject to criminal and civil sanctions prescribed in HIPAA.

After considering public comment on the final rule, HHS Secretary Tommy G. Thompson allowed it to take effect as scheduled, with compliance for most covered entities required by April 14, 2003. (Small health plans have an additional year.)

In March 2002, HHS proposed specific changes to the privacy rule to ensure that it protects privacy without interfering with access to care or quality of care. After considering public comments, HHS issued a final set of modifications on Aug. 14, 2002. Detailed information about the privacy rule is available at http://www.hhs.gov/ocr/hipaa.

SECURITY STANDARDS

In February 2003, HHS adopted final regulations for security standards to protect electronic health information systems from improper access or alteration. Under the security standards, covered entities must establish procedures and mechanisms to protect the confidentiality, integrity and availability of electronic protected health information. The rule requires covered entities to implement administrative, physical and technical safeguards to protect electronic protected health information in their care. The standards use many of the same terms and definitions as the privacy rule to make it easier for covered entities to comply. Most covered entities must comply with the security standards by April 21, 2005, while small health plans as defined by HIPAA will have an additional year to come into compliance.

EMPLOYER IDENTIFIER

In May 2002, HHS issued a final rule to standardize the identifying numbers assigned to employers in the health care industry by using the existing Employer Identification Number (EIN), which is assigned and maintained by the Internal Revenue Service. Businesses that pay wages to employees already have an EIN. Currently, health plans and providers may use different ID numbers for a single employer in their transactions, increasing the time and cost for routine activities such as health plan enrollments and health plan premium payments. Most covered entities must comply with the EIN standard by July 30, 2004. (Small health plans have an additional year to comply.)

ADDITIONAL STANDARDS

Led by CMS, HHS is currently developing other administrative simplification standards. HHS has published proposed regulations for national identifiers for health care providers - and is now reviewing public comments and preparing final regulations. HHS also is working to develop other proposed standards, including a national health plan identifier and additional electronic transaction standards. In addition, HHS is developing regulations related to enforcement of the adopted standards. The status of key standards required under HIPAA follows:

National provider identifier. In May 1998, HHS proposed standards to require hospitals, doctors, nursing homes, and other health care providers to obtain a unique identifier when filing electronic claims with public and private insurance programs. Providers would apply for an identifier once and keep it if they relocated or changed specialties. Currently, health care providers are assigned different ID numbers by each different private health plan, hospital, nursing home, and public program such as Medicare and Medicaid. These multiple ID numbers result in slower payments, increased costs and a lack of coordination.

National health plan identifier and other HIPAA regulations. HHS is working to propose standards that would create a unique identifier for health plans, making it easier for health care providers to conduct transactions with different health plans. HHS is also working to develop additional transaction standards for attachments to electronic claims and for a doctor's first report of a workplace injury. In addition, HHS is developing a proposed rule on enforcement of the HIPAA requirements. As with other HIPAA regulations, HHS will first consider public comment on each proposed rule before issuing any final standards.

Personal identifier on hold. Although HIPAA included a requirement for a unique personal health care identifier, HHS and Congress have put the development of such a standard on hold indefinitely. In 1998, HHS delayed any work on this standard until after comprehensive privacy protections were in place. Since 1999, Congress has adopted budget language to ensure no such standard is adopted without Congress' approval. HHS has no plans to develop such an identifier.
Note: All HHS press releases, fact sheets and other press materials are available at http://www.hhs.gov/news.

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FINANCIAL POLICIES

As patients contemplate aesthetic medical spa treatments, they frequently need information about the financial aspects of their treatment and the various payment methods available to them. Our staff members are specially trained in the financial options available to our patients, and they are readily available to assist you with these issues in any way that you may require. Because we provide elective cosmetic procedures, the care provided at **[INSERT PRACTICE NAME]** is not covered by any medical insurance programs, and we do not participate in any such plans.

PAYMENT OPTIONS

Payment for all medical spa procedures is due at the time of the treatment. For specially packaged or grouped treatments, payment for the entire package is due at the time of the first scheduled treatment. **A credit card is required to reserve an appointment for treatment scheduled in advance**. We provide a number of payment options which may be used individually or combined according to your desires:

CASH OR CHECK: Personal check drawn on a local bank, cashier's check, or cash
MAJOR CREDIT CARDS: VISA, MasterCard, and American Express
CARE CREDIT: Our staff can assist you in obtaining a special line of credit through Care Credit for financing medical procedures if you wish.

CANCELLATION AND REFUNDS

We understand that a situation may arise that could force you to cancel or postpone your treatment. Please understand that such changes affect not only our staff but our other patients as well, and we therefore request your courtesy and concern. If you need to cancel your appointment, please allow 24 hours to notify us of the cancellation. Should we receive less than 24 hours of notification, or should you fail to keep your appointment, your credit card will be charged **$50** for the visit.

THERE CAN BE NO REFUNDS FOR SERVICES ALREADY PROVIDED.

In the event that a package or series of treatments has begun, these services will be considered to have been rendered even though the full series may not have been completed. Should you wish to discontinue your treatment in the midst of a series, credit for the pro rata share of unused treatments at the discounted package price may be extended, and may be used to purchase other treatments or products offered by **[NAME OF PRACTICE]**, or it may be transferred to another individual to be used in exchange for treatments or products of comparable value to the credit.

REVISIONAL TREATMENT OR TREATMENT OF COMPLICATIONS

The practice of medicine and surgery is not an exact science, and medical spa treatments are the practice of medicine. Although good results are anticipated, **there can be no guarantee or warranty, expressed or implied, by anyone as to the actual results you may get.** Occasionally additional treatments and/or treatment for problems or complications may be required. These could result in additional charges for which you may be responsible. Your insurance, if you have it, may or may not cover the expenses related to actual complications or other medically related problems arising out of treatment at **[NAME OF PRACTICE]** I acknowledge that I have read and fully understand the foregoing Financial Policies and my obligations related thereto,

_____ _____
Patient Signature Date

These Financial Policies are subject to change without notice. If you have any questions or need assistance with any financial matters relating to your treatment, please contact our office for help.

PATIENT SATISFACTION QUESTIONNAIRE

In order that we may better serve our patients, would you please take a few moments to rate our service?

	Excellent	Good	Fair	Poor
1. The aesthetic procedure was discussed to my satisfaction prior to the event?	_____	_____	_____	_____
2. The date and time of the procedure was clearly reviewed?	_____	_____	_____	_____
3. The events of the aesthetic treatment proceeded on time?	_____	_____	_____	_____
4. The environment was comfortable and organized?	_____	_____	_____	_____
5. The staff were available to answer questions and explain procedures?	_____	_____	_____	_____
6. Information regarding the post procedure care was clearly reviewed?	_____	_____	_____	_____
7. Post-operative instructions were adequate?	_____	_____	_____	_____
8. Prescriptions were given and discussed?	_____	_____	_____	_____
9. The facility's hours were convenient?	_____	_____	_____	_____
10. The staff were courteous, efficient and professional?	_____	_____	_____	_____
11. Pre-treatment information was helpful?	_____	_____	_____	_____
12. Procedure costs were clearly reviewed?	_____	_____	_____	_____
13. Overall impression of facility/procedure?	_____	_____	_____	_____

Other:

1. What did you find most informative about the facility? ___ Staff ___ Brochure
2. What did you like most about the facility?

_____

_____

3. What did you like least?

_____

_____

4. How did you learn about the facility?

_____

5. Were there any problems that you did not anticipate?

_____

_____

5. Please give us two suggestions on how we might improve our service.

(1) _____

(2) _____

Name: _____
Optional

Procedure Date: _____