SCITON INFORMED CONSENT

INTRODUCTION

Lasers have been used by surgeons as a surgical instrument for many years. Laser energy can be used to cut, vaporize, or selectively remove skin and deeper tissues. There are many different methods for the surgical use of lasers.

Conditions such as wrinkles, sun damaged skin, scars and some types of skin lesions/disorders may be treated with the laser. In some situations, laser treatments may be performed at the time of other surgical procedures.

Skin treatment programs, such as Obagi or Triluma, may be used both before and after laser skin treatments in order to optimize the treatment and 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 (dermabrasion or excisional surgery) may be substituted. In certain situations, the laser may offer a specific therapeutic advantage over other forms of treatment. Alternatively laser treatments procedures in some situations may not represent a better alternative to other forms of treatment that involve skin treatments or surgical procedures.

Risks of Erbium: **YAG Laser Treatment of Skin** – There are both risks and complication 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 our surgeon to make sure that 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. 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 such as Valtrex may be prescribed and taken both prior to and following the laser treatment procedure in order to suppress an outbreak from this virus. Should any type of skin infection occur, additional treatment 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 burn. Burns are rare, yet represent the effect of heat produced within the tissues by laser energy. Additional treatment may be necessary to treat the laser burns.

Color Change – Laser treatments may potentially change the natural color of your skin. Skin redness usually lasts two weeks to three months and occasionally up to six 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 (Isotretinoin) – Accutane is prescription medication used to treat certain skin diseases. This drug may impair the ability of the 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 12 months to recover from Accutane before undergoing laser skin treatment procedures.

Fire – Inflammable agents, surgical drapes and tubing, hair and clothing may be ignited by laser energy. Laser energy used in the presence of supplemental oxygen increases the potential hazard of fire. Some anesthetic gases may support combustion.

Laser Smoke (plume) – Laser smoke is noxious to those who come in contact with it. This smoke may represent a possible bio-hazard.

Bleeding – prolonged bleeding is rare following erbium:YAG laser skin treatment procedures. It is not unusual for minor oozing following the procedure. Should significant bleeding occur, additional treatment may be necessary.

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 an 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 previously treated with chemical peels or dermabrasion, or damaged by burns, 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 and additional treatments may be necessary.

Distortion of Anatomic Features – Laser skin treatments can produce distortion of the appearance of the appearance of the eyelids, mouth and other visible anatomic landmarks. The occurrence of this is not predictable. Should this occur, additional treatment including surgery may be necessary.

Unsatisfactory Result – There is the possibility of an unsatisfactory result form these procedures. Erbium: YAG laser treatment procedures may result in an 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.

Pain – Very infrequently chronic pain may occur after laser skin treatment procedures.

Allergic Reactions – In rare cases, local allergies to tape, preservatives used in cosmetics or topical preparations have been reported. Systematic reactions, which are more serious, may result from drugs used during surgery and prescription medications. 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. No technique can reverse the signs of skin aging. Additional surgical procedures 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.

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, 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 the laser 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. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revisional surgery or treatments would also be your responsibility.

DISCLAIMER – Informed-consent documents are used to communicate information about the proposed surgical treatment of a condition along with disclosure of risks and alternative forms or 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. Informed-consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

INFORMED CONSENT FOR SURGERY - SCITON CONTOUR LASER TREATMENT OF THE SKIN

- 1. I hereby recognize Dr. Stacey Folk, MD, Michael Bateman, MD, D. Jill Buckner, PA-C and Heather Palmer, RN and such assistants as may be selected to perform the laser treatment.
- 2. 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 complication, injury and sometimes death.
- 3. I acknowledge that no guarantee has been given to me by anyone as to the results that may be obtained.
- 4. I consent to the photographing, before, during and after the procedure(s) for medical, scientific or educational purposes, provided my identity is not revealed in the pictures.
- 5. 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

Patient or Person Authorized to sign for Patient:	Date:
Witness:	

LASER/BBL PRE-TREATMENT ADVISOR

- o Avoided sun exposure for 2 weeks prior to procedure.
- No Accutane for at least 9 months.
- Avoid unnecessary medications that could increase photo-toxicity. Antibiotics such as tetracycline derivatives, Bactrim, and flouroquinolones are most common).
- o Using Retin A, Clear, Blender, or Triluma for at least 2 weeks if fair skinned, 4-6 weeks if dark skinned prior to procedures is important to minimize hyperpigmentation.
- Take antiviral (Valtrex) if having Halo or ablative procedure (Profractional, MicrolaserPeel, or resurfacing) 1 day prior, day of procedure, and continue daily until gone. You must reschedule if you have an active cold sore.
- o Continue to avoid sun for 2 weeks following BBL and/or Halo, and for 1 to 3 months after an ablative laser. Sunscreen use and physical barriers like a hat or visor are essential.
- O Continued use of good skin care once healed will maximize and prolong results. All products can be used immediately following BBL treatments. Clear, Blender, and Triluma can be started 2 weeks following Halo and Retin A at 4 weeks. Timing varies after ablative lasers, so be sure you understand your specific instructions. In general, Hydroquinone products start 2 weeks after healed, and Retin A is gradually introduced 2-4 weeks later.

MicroLaser Peel (MLP), ProFractional (PFX), and Resurfacing Treatment Instructions

The Scition Erbium laser is an "ablative" treatment which means portions of your skin will be vaporized and the resulting skin will be raw until healed. The target of the laser is water that resides in the deeper layers of your skin, so keeping skin well-hydrated hydrated and moisturized skin leading up to your procedure will provide superior results. There are a variety of treatment options available allowing the laser treatment to be individually tailored to an individual's needs with respect to: skin type, degree of pre-existing damage, and available down-time. ProFractional treatments are a dot matrix type pattern that heals the most quickly. MicroLaser Peel is full field removal of skin, and Resurfacing is an even deeper version. A combination of these treatments is most commonly performed. The time to healing can only be estimated from patient to patient. Patients can expect an improvement with each treatment, but complete resolution of wrinkles is not a realistic expectation.

In the short-term redness, you should expect swelling, visible grid pattern, pain, and sensitivity. Long term there can be pigmentation problems (hyper or hypopigmentation), and potential scarring. For this reason we err on the side of safety, preferring a series of procedures.

PREPARING FOR YOUR LASER

- Begin prepping your skin with Hydroquinone 4% and Retin-A (tretinoin) for a minimum of one month prior to your procedure. A longer time is preferred for darker skin types. Hydroquinone (found in Obagi's Blender and Clear) corrects pigmentation in the skin and reduces hypermigmentation during the healing phase. Retin-A also reduces pigment, smooths the outer layers of the skin for an even treatment, and revs up your collagen production. Triluma which contains Hydroquinone, Retin-A, and a steroid can also be used. Alternatives are available if you cannot use these products. These products can dry your skin so be sure to use extra hydration, especially in the days prior to your procedure. For this same reason it recommended that you **stop using Hydroquinone and Retin-A 3 days before your procedure**.
- Avoid sun exposure for at least 2 weeks prior to your procedure.
- You may not use Accutane within 12 months of your procedure.
- Other medications to avoid the week prior are Tetracycline antibiotics and blood thinners such as Aspirin, Coumadin, and Xeralto.
- Antivirals (Valtrex or Acyclovir) are used around the time of the procedure to prevent Herpes or cold sore outbreaks. Patients who have a history of cold sores should start taking their medication 2 days prior to their procedure and everyone else should start one day prior. You should continue taking this medication until your skin is re-epithelialized or healed over. If you have an active cold sore your procedure needs to be rescheduled. If you feel you are getting a cold sore during the healing phase, please call the office.
- Your skin will be extremely sensitive to potential allergens (like perfumes and dyes) until it is healed over so we recommend washing the towels, pillow cases, headbands, and dedicated shirts in something

like Tide Free or Dreft. Running the load a second time without detergent or fabric softener is another great option.

THE DAY OF YOUR PROCEDURE (IN THE OPERATING ROOM)

- Shower in the morning and come in with clean skin (moisturizer and sunscreen is okay).
- Take your Valtrex the night prior, unless it is scheduled for later in the day where you can take in the morning with a small sip of water.
- Bring a soft headband to keep your hair off your face.
- Bring a dark colored towel so when you leave the hospital you can protect your clothes from the Aquaphor and blood.

THE DAY OF YOUR PROCEDURE (IN THE OFFICE)

- Shower in the morning and come in with clean skin.
- If you have signed your consent forms you can take 1 or 2 Valium and your Valtrex before coming into the office. Bring the remaining Valium and pain medications with you.
- Bring a soft headband to keep your hair off your face.
- Bring a dark colored towel and hat so when you leave the office you can protect your clothes from the Aquaphor and blood and your face from the sun.
- Arrange to have a ride home.

IMMEDIATELY FOLLOWING YOUR PROCEDURE

- Reapply the Aquaphor or other occlusive barrier around the clock taking care to cover all treated areas. This occlusive barrier is needed to provide a protective layer that will hold moisture into the skin and provide protection to the skin from pollutants in the air as the skin heals. Reapply the occlusive barrier as often as needed. **Do not allow the treated area to dry out.** Having a humidifier or cold air vaporizer at your bedside can provide additional moisture.
- Cleanse the skin two times a day with plain, lukewarm water and a gentle cleanser; (Cetaphil, Obagi Gentle Cleanser, Elta MD or plain Baby Shampoo) beginning the morning after the treatment. Use your hands to gently apply the cleanser and water and finish by patting dry with a soft cloth. Be careful not to rub the treated area. When showering, be sure to wash your hair behind you to avoid getting shampoo directly on the treated area. Baby Shampoo can touch the lasered skin without concerns. Immediately reapply the Aquaphor after cleansing or showering.
- A cold compress or an ice pack can be used to provide comfort if the treated area is especially warm. This is typically only needed within the first 12 hours after the treatment. You can do also continue vinegar soaks to help calm irritation. Put 1 tsp. of white vinegar into 2 cups water. Saturate a wash cloth and place on face. Repeat several times daily as desired. Store in refrigerator.
- For the PFX, oozing may persist for 24 hours after the treatment. For MicroLaserPeel and Resurfacing this may continue for a week. Bleeding, oozing, and an exudate generally begin within 24 hours post treatment

and should be allowed to come off naturally. **DO NOT PICK, RUB, OR FORCE OFF ANY SKIN DURING THE HEALING PROCESS. THIS COULD RESULT IN SCARRING AND INFECTION!** Gently washing the skin more frequently will help to promote the peeling process. Some areas may heal much faster than others.

- Redness normally persists for days to months depending upon the depth of the treatment. Some areas may stay red longer (such as around the eyes). You can wear make-up when your skin has healed.
- Swelling is typically a completely normal short-term response. Use of a cold compress or ice packs will help to relieve the swelling. To avoid further swelling, you may choose to sleep in an elevated position several nights after the treatment.
- Continue to take your antiviral (Valtrex) until all your skin has healed.
- Post treatment discomfort may be relieved by oral pain relievers; i.e. Extra Strength Tylenol or prescription pain medication.

LONGER TERM AFTER YOUR PROCEDURE

- You will be able to tell when your skin can tolerate a regular moisturizer (Medical Barrier Cream) and sunscreen (usually day 2-7 depending on procedure). After a shower your skin will appear red itching and a rash. If this occurs during the healing phase begin oral Benadryl and use topical Hydrocortisone cream every few hours. If this does not improve within 24 hours call the office.
- Avoid direct sunlight for up to 2 months post treatment. Sunscreen and physical barriers like a hat or umbrella are strongly encouraged. Sun exposure increases hyperpigmentation, and your skin is extremely sensitive to this following your procedure.
- Once skin has healed (no longer wearing the occlusive barrier) you may begin to wear makeup. If you are able to wear makeup, a sunblock should be worn on a daily basis to help prevent any hyperpigmentation issues that could be caused by direct and indirect sunlight.
- Avoid strenuous exercise and sweating until after skin has healed.
- Best results are obtained when lighter treatments are performed as a series. The ProFractional treatment may
 be repeated at 4-6 weeks, the MicroLaserPeel & ProFractional combination should be scheduled around 6-8
 weeks apart.

• Starting 2-4 weeks after your skin is healed you may resume using your Hydroquinone (Blender or Clear). After another week or two you can slowly reintroduce your Retin A. The timing will be based on the aggressiveness of your treatment and the sensitivity of your skin.

RECOMMENDED SHOPPING LIST

- Aquaphor
- Hydrocortisone ointment or cream
- Benadryl
- Baby Shampoo/ Gentle cleanser
- Soft headband
- Gauze pads