



# **PROFILE™ CONTOUR™ 2.94-μM LASER MODULE: PROFRACTIONAL™ SAFE START PROTOCOL**

The following protocol is a safe start guide based upon the clinical observations of experienced physicians.

## **Introduction**

Over recent years facial rejuvenation has become an attractive option for patients looking to enhance the tone, texture and the overall appearance of their skin. Aesthetic concerns such as fine lines, wrinkles, acne scarring and pigment can be addressed and treated with excellent results using ablative treatment modalities. However, these results usually come with long periods of downtime that today's patients won't often tolerate. The issue of downtime led to the development of non-ablative technologies that promise less downtime, but not the same dramatic results.

Fractional resurfacing is a popular new choice and has been receiving a lot of attention. The first generation of fractional technology delivered non-ablative Er:Glass fractionated laser energy onto the skin, covering only a portion of the total scanned area and leaving bridges of intact skin. That sped up healing and made the procedure more comfortable. However, due to the bulk tissue heating, the procedures done with those devices are still quite painful, which is a serious issue for many patients.

When choosing a system for facial rejuvenation the question is this: which laser is delivering enough energy to actually make a visible difference without the low tolerability, long downtime and multiple treatment series? The ideal rejuvenation procedure offers the patient a quick and relatively painless yet effective treatment of their photo-damaged skin. Patients want the results of ablative technologies with the limited downtime of non-ablative treatments.

Sciton has introduced the ProFractional™, which requires little or no anesthesia, fewer treatment sessions, has no consumable components, and offers results comparable to more aggressive treatments. Many patients can return to work the next day. The ProFractional has raised the cosmetic standard for fractional facial rejuvenation and enhances Sciton's repertoire of reliable, durable lasers that provide excellent clinical outcomes and high patient satisfaction.

## **ProFractional vs. Fractional Technology**

Like early fractional devices, Sciton's ProFractional works on the principle of fractionated photothermolysis. The difference lies in the delivery of the energy. Due to its efficient water absorption characteristics, ProFractional 2940-nm Er:YAG laser is able to penetrate deeply into the dermis by ablating narrow, clean channels to a selected depth and instantly removing necrotic tissue. These channels are surrounded by healthy tissue, speeding healing time and

reducing downtime for the patient. As opposed to non-ablative technologies, which create large zones of thermal necrosis, ProFractional energy delivery is limited to the narrow channels, minimizing patient discomfort. The depth and density of these channels can be easily and precisely adjusted to customize treatment for each patient. This is a revolutionary advancement in fractional technology. And the system doesn't require the purchase of a new laser. ProFractional is a modular upgrade to any existing Sciton Profile™ platform.

## **Mechanism of Dermal Resurfacing with ProFractional**

By delivering energy deep into the dermal tissue, ProFractional selectively injures collagen molecules, causing wound-healing response and stimulating fibroblast activity. Fibroblasts turn on new collagen production, rejuvenating the collagen matrix and plumping the skin from the inside out. That's why with ProFractional a practitioner can effectively treat wrinkles, scars, pigment, and skin tone and texture.

**IMPORTANT: Treating with dirty lenses, overlapping scans or at settings much higher than those recommended by the protocol may lead to undesirable outcomes. Attention to technique and conservative treatment are recommended. This guide is not intended as a replacement for clinical training, a preceptorship or supervised experience. Please follow the instructions in the Operator's Manual for the system you will be using.**

## **1. PRE-TREATMENT CONSIDERATIONS**

***CAUTION: Selection of patients must include evaluation of Fitzpatrick Skin Type (I-VI). With ProFractional you can safely and comfortably treat patients with Fitzpatrick skin types I through IV. ProFractional is an ablative procedure without the coagulation that could lead to long term or permanent hypo- or hyper-pigmentation issues. Experience with darker skin types (V and VI) is limited at this time. The evidence so far suggests that ProFractional can treat darker skin types without pigmentary changes but it is recommended that a test spot is done on darker skin type patients first. Some patients may experience transitory lines of demarcation with more aggressive ProFractional treatments. These lines resolve in a few days after treatment.***

## Classification of Skin Types

### Fitzpatrick Scale

The following table offers a broad guidance to identifying skin types based on hair, skin and eye color as well as sun reaction.

Type	Hair Color	Skin Color	Eye Color	Sun Reaction
I	Red	Light	Blue-green	Burn, never tan
II	Blonde	Light	Blue	Burn, may tan
III	Brown	Medium	Brown	Burn, then tan
IV	Brown-black	Moderate brown	Brown-black	Tan
V	Black	Dark brown	Dark	Tan
VI	Black	Black (African)	Dark	Tan

#### 1.1. BEFORE TREATMENT

Patients on Retin-A, Retinol, AHA or any other acid peel treatment regimen should be advised to stop using it 3 days before the treatment. All patients, and especially those with a history of herpes simplex infections, should be put on Valtrex or another anti-viral medication.

To prevent post-treatment swelling and burning sensation that may occur with some patients, a non-steroidal anti-inflammatory medication (e.g. Motrin) may be administered 20 minutes prior to the treatment.

#### 1.2. CLEAN SKIN

Use a mild cleanser to remove any dirt, makeup, or moisture from the treatment area. Follow with an alcohol wipe. Allow alcohol to evaporate before treatment. Use special care around the eyes.

#### 1.3. ANESTHESIA

Use a topical preparation, as needed, to alleviate discomfort for sensitive patients or sensitive areas prior to treatment. Read the manufacturer's guidelines for the application and duration of the anesthetic. Remove before treatment with mild soap and water or an alcohol swab, then plain water. Dry the area thoroughly before treatment.

#### 1.4. HANDPIECE CLEANING

Prior to each treatment, clean the handpiece optics with an alcohol swab. Check the lenses during long procedures and clean as necessary.

## 1.5. STAND-OFF DISINFECTION

Stand-offs should receive high-level disinfection prior to each use. Use the disinfectant manufacturer's instructions on high-level disinfection procedure. Gloves should be worn when handling a stand-off during and after the treatment.

## 1.6. EYE PROTECTION

Always use eye protection for the patient, the operator, and anyone in the laser treatment room during the treatment.

## 1.7. TREATING AREAS OTHER THAN THE FACE:

### 1.7.1. Neck and Chest

The epidermis of the neck and chest is both thinner than that of the face and has fewer adnexal healing structures. Peels beyond 100 microns in depth and 5% in density are not recommended as a single event. Re-treatment may occur as early as 8 weeks. This procedure may not be ideal for patients with known healing deficiencies.

### 1.7.2. Hands and other Body Areas

The epidermis of the hands and general body surfaces is both thinner than that of the face and has fewer adnexal healing structures. Peels beyond 100 microns in depth and 5% in density are not recommended as a single event. Re-treatment may occur as early as 8 weeks. This procedure may not be ideal for patients with known healing deficiencies.

***CAUTION: Particulate debris on the optics of the scanner/handpiece may result in laser beam scattering and an incorrect setting for fluence. Concurrent use of a high volume particulate evacuator (smoke evacuator) is mandatory for both safety and convenience reasons when the stand-off without a contact plate is used.***

## 2. SETTING TREATMENT PARAMETERS

### 2.1. DELIVERY

#### 2.1.1. SCANNER/HANDPIECE

The ProFractional SCANNER/HANDPIECE is used for ProFractional treatments. Care should be taken to apply adjoining scans without gap or excessive overlap of the previously scanned area. The stacking of consecutive pulses should be monitored and avoided in most circumstances.

The treatment area within the scanned pattern may be adjusted from 1.5 to 60%. The total scanned area may be varied from 6x6 mm to 20x20 mm. The removable stand-off is used to position the focal plane of the laser energy onto the skin surface. The disinfected stand-off should be attached to the handpiece and maintained in continual contact with tissue during laser use for precise focus and uniform delivery. The stand-off can be used with or without a contact plate. The scanner should always be held perpendicular to the skin surface for consistent results.

***IMPORTANT: The scanner/handpiece should always be held perpendicular to the treated area for consistent results. A test pattern from the scanner should be fired on a safe non-tissue target (wooden tongue depressor, etc.) to assure pattern size, uniformity, and confocal presence with the visible indicating beam before the procedure begins.***

### **2.1.2. ABLATION DEPTH**

The ABLATION DEPTH required depends on the condition to be treated. The recommended ablation depth for general facial rejuvenation with ProFractional is 75 to 200 microns done in a single pass. Deeper penetration may be required for deep wrinkles, particularly for perioral or periorbital areas. The laser may be manually set to the required ablation depth.

For mild scars a shallow depth of 100 microns is effective. For aggressive treatment of deep scars, depth settings may be increased to 400 or even 800 microns. Individual scars can be treated as minimally or as aggressively as necessary to create an overall evenness of the skin. A single pass treatment is recommended for most patients with scars.

Patient response can vary. Generally, treating at higher depths accounts for higher energy delivery and longer healing. Ablation depth should be selected based on the condition treated, expected outcome, patient pain tolerance, and expected 'downtime' for healing after assessing the individual patient needs. The desired response is erythema within a few minutes of laser application. The redness and healing (often similar in appearance to varying degrees of sunburn) will increase with the depth of ablation and will vary by patient.

Setting ablation depth higher than needed may lead to undesired thermal damage and prolonged downtime.

### **2.1.3. TREATMENT AREA**

The TREATMENT AREA required depends on the condition to be treated. The recommended coverage area for facial rejuvenation with ProFractional is 2% to

15% of the scanned area. For scars, 4 or 5% treatment area is recommended. The laser may be manually set to the required treatment area.

Patient response can vary. Generally, treating larger portion of the skin accounts for more effective results and longer healing. Setting coverage area higher than needed may lead to undesired thermal damage and prolonged downtime.

Table 1. Treatment Starting Parameters

<b>Application</b>	<b>Treatment Area (%)</b>	<b>Ablation Depth (µm)</b>
Facial rejuvenation	2 - 15	75 - 200
Shallow acne scars	4 - 5	100
Deep acne and hypertrophic scars	4 - 5	400 - 800

### 3. TECHNIQUE

#### 3.1. PATIENT POSITION

It is often easiest to lay the patient horizontally (supine or dorsal recumbent) and stand directly behind the patient's head. Elevate the table so the patient's head is as high as the top of the laser console. Sitting upright during ablation of the face or other body area is not contraindicated.

#### 3.2. TEST AREA

To confirm that laser and accessories are performing normally, it is useful for the operator to test on a nonflammable inanimate object like a wooden tongue depressor.

Treating a test area at the beginning of a patient's first treatment can establish their response threshold and help them understand the audible and sensory components of the treatment.

***IMPORTANT: A test pattern from the scanner or handpiece should be fired on a safe non-tissue target (wooden tongue depressor, etc.) to assure pattern size, uniformity, and coaxial presence with the visible indicating beam before the procedure begins.***

### 3.3. PLUME EVACUATION

When using a stand-off without a contact plate, a plume evacuation should be used. The distal end of the plume evacuator should be as close as possible to the ablative site. Tubing not within one inch of the operative site will capture less than 50% of the plume and debris from the laser site.

## 4. TREATMENT METHOD

Set the depth and coverage parameters, adjust the scanned area, and perform a single-pass treatment. Match the “trailing edge” of the next scan to the “leading edge” of the previous scan. The computer-guided scanner will give a uniform fractional treatment with selected beam placement within the scan.

***IMPORTANT: Always perform a single-pass treatment only.***

***CAUTION: Do not stack pulses or overlap consecutive scans. Repeated scans in the same location may lead to subsequent epidermal or dermal injury.***

***CAUTION: Do not allow combustibles or flammables, including drapes, in the laser treatment area. Fire prevention/control methods should be in place.***

## 5. TREATMENT GOALS

Patient response can vary. Generally, the healthier the skin and/or the patient, the less the redness from treatment and the faster the healing response. Ablation depth and treatment area should be selected based on expected outcome, patient pain tolerance, and expected ‘downtime’ for healing after assessing the individual patient needs. The desired response is erythema within a few minutes of laser application. Incidental pinpoint bleeding may occur which will stop within a few minutes after the treatment. The redness and healing (often similar in appearance to varying degrees of sunburn) will increase with the ablation depth and the treatment area, and will vary by patient.

## 6. POST-TREATMENT CONSIDERATIONS

### 6.1. OBSERVATIONS

Erythema, edema and a sunburn sensation will be noticed in the treatment area for a few days after the treatment. Incidental pinpoint bleeding may occur, which will subside within a short time after the treatment without any intervention. Occasional

patterned hyperpigmentation may occur but it will resolve in a few days. The healing time will differ, depending on the treatment settings used.

## 6.2. INTERVENTION

Immediate post-treatment care includes a simple moisturizer, like Aquaphor or Elta. It should be applied for at least 24 hours after the treatment. A cooling mist spray can also help cool and comfort the skin as the moisture evaporates. It is important for the treated area to remain soft and pliable during healing. Sunscreen should be applied for at least a month after initial healing, and it is recommended to avoid sun exposure until redness has resolved. Physical blocks, such as a hat or a scarf and sunglasses, should also be used.

The day after the treatment it is recommended to wash the treated area with a mild, gentle soap-free cleanser (e.g. Cetaphil cleanser) and then apply a moisturizer (e.g. Cetaphil or Neutrogena moisturizer). The moisturizer should be re-applied as necessary to prevent the area from becoming dry and crusted. Sunscreen should be applied on top of moisturizer.

It is recommended to put patients on anti-viral medication (e.g. Valtrex or Famvir) after the treatment.

Patients should be advised not to use Retin-A, Retinol or AHA for 1 – 2 weeks following the treatment. Patients should not participate in any strenuous physical exercise for 24 hours following the treatment.

Patients should be advised **not** to use any skin care products except for the ones recommended by the physician to avoid possible allergic reactions. For example, antibiotic ointments, like Bacitracin or Neosporin, can cause extreme swelling. And it is not recommended to apply makeup prior to initial healing.

If redness persists for several days, over-the-counter Hydrocortisone 1% cream or another mild steroid may be used as directed. In case of prolonged swelling, corticosteroids (e.g. Methylprednisolone or Medrol dosepak) can be prescribed. If itching occurs, an antihistamine (e.g. Benadryl) can be used to alleviate discomfort.

***IMPORTANT: Patients should be advised to strictly adhere to physician recommended post-treatment regimen to avoid any post-operative complications.***

## 6.3. INTERVAL

Recommended time interval between treatments is 3 – 6 weeks with the average of 4 weeks. Re-treatment in an earlier period may create additional discomfort or sensation at time of treatment. For facial rejuvenation a short series of up to three treatments may be recommended for optimal results. Acne scars may require four or five treatments using conservative protocols.

## 7. CONCURRENT PROCEDURES

COMBINATIONS – ProFractional can be combined with MICROLASERPEEL for more enhanced results in one treatment. The recommended combination sequence is doing MICROLASERPEEL first, followed by ProFractional. This sequence provides the total maximum efficacy of the combined treatment. Pre- and post-treatment care is standardized. A topical numbing cream can be used before MLP, immediately followed by ProFractional. Moisturizer, a cooling mist spray, or both after the treatment is recommended.

**For MICROLASERPEEL treatment settings refer to MICROLASERPEEL Safe Start Protocol.**

## 8. CONCLUSIONS

Patients choose ProFractional over full face resurfacing because of it provides a more comfortable treatment experience and rapid healing with very little downtime. Improvement increases after each treatment but even after just one treatment the patient will notice a difference. There is no need for the patient to commit to a large number of treatment sessions, making the procedure very patient-friendly. Collagen remodeling takes time, so the full effect of a single treatment is not immediately apparent.



# PROFILE™ CONTOUR™ 2.94-μm LASER MODULE: PROFRACTIONAL™ SAFE START PROTOCOL SUMMARY

## 1. Pre-Treatment:

- Clean area to be treated. All make-up removed.
- Anesthesia - Use a topical preparation as necessary. Remove before treatment.
- Clean handpiece optics prior to each treatment
- Disinfect stand-off in high-level disinfectant prior to each treatment
- **Eye Protection - Always use eye protection for the patient, the operator and anyone in the laser treatment room**
- Test fire for alignment and operation.
- Prepare adequate plume evacuation when using a stand-off without a contact plate.
- Position patient either sitting upright or lying supine for facial treatment.

## 2. Treatment:

- Use adequate plume evacuation when using a stand-off without a contact plate.
- Set to appropriate depth and treatment area and desired scanned area.

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- POSITION HANDPIECE scanner perpendicular to the treated area so that the stand-off is placed in full contact with tissue.
- TREAT with non-overlapping scans.

## 3. Post-Treatment:

- OBSERVATIONS - Erythema and edema for a few days after treatment.
- INTERVENTION – A moisturizer will provide comfort after treatment and keep the skin soft and pliable. Patients should strictly adhere to post-treatment regimen to avoid any post-operative complications.
- INTERVAL - between ProFractional treatments is 2 - 6 weeks.

## 4. If combined with MICROLASERPEEL procedure in one visit, perform ProFractional treatment after MICROLASERPEEL.

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