



## **PROFILE BBL ST ACCESSORY: COSMETIC SKIN APPLICATION FOR TREATING LAXITY**

### **SAFE START PROTOCOL**

**FDA Clearance is for selective photocoagulation of soft tissue in conjunction with an integral thermo-electric cooler for use in cooling the epidermis at the treatment site prior to, during and after treatment to reduce discomfort and minimize thermal injury to non-target skin and skin structures.**

The following protocol is a safe start guide based upon the clinical observations of experienced physicians for using this technique to selectively target and treat dermal collagen. The result is partial coagulation and contraction of collagen.

#### **Introduction**

The proper combination of skin surface cooling and pulsed light treatment can create a beneficial rise in temperature at a desirable point below the skin surface. Cooling the surface of skin will alter its subsurface temperature gradient. The temperature of the BBL cooling plate and the fluence delivered from the BBL will determine the temperature profile beneath the surface of treated skin. The following guide is a safe starting protocol for the use of the BBL/ST Accessory.

#### **Photothermal Skin Heating**

The epidermis is a robust and resilient structure at the surface. It functions as a physical barrier to protect the deeper dermis, and retain the skin's hydration. It is less hydrated than the dermis resulting in less absorption of energy at infrared wavelengths than in the dermis, since infrared energy is preferentially absorbed in water and collagen. The highest absorption, and thus the highest temperature, will occur below the epidermis in the more hydrated dermis. The result is a higher temperature near the region of the dermis. By clamping the outer skin surface at a fixed temperature with the BBL cooling plate, the peak temperature from laser treatment can be biased toward shallower or deeper regions of the skin.

#### **Surface Cooling**

An examination of the dermal anatomy will show that the papillary dermis is in contact and protrudes into the epidermis. It is therefore impossible to cool the epidermis without some cooling of the papillary dermis. Attempts to selectively pre-cool the epidermis by pulsed

cooling followed by laser are equivalent to contact surface cooling with simultaneous laser treatment at the depths and times of interest for collagen remodeling.

The thermal profile in the skin will have a maximum temperature below the epidermis at a depth determined by the surface temperature and the absorption characteristics of the infrared pulsed light energy in tissue. It is thought that collagen strands are denatured and contract in response to high temperatures. The temperature for this effect is inversely proportional to the exposure time. Ideally, the peak temperature is just above the threshold for initiating collagen coagulation, but not enough to cause full thickness necrosis, By using long exposure times of several seconds and lower temperatures the risk of full thickness coagulation can be reduced.

Contact surface cooling clamps the skin surface at a predetermined temperature so that treatments will be consistent regardless of the patient's nominal skin temperature. The thermodynamic properties of skin are very similar for all patients and a reproducible thermal response will be achieved by setting surface cooling temperature, BBL fluence, and BBL pulse width. Adjusting these settings will allow you to adjust the treatment to different skin conditions with reproducible treatment temperatures.

**IMPORTANT: Treating with excessive fluence or overlapping pulses may lead to undesirable outcomes, including blisters, depressions and transient hyperpigmentation, all due to overheating of tissue. Attention to technique and conservative treatment are recommended. This guide is not intended as a replacement for clinical training, preceptorship or supervised experience. Please follow the instructions in the Operator's Manual for the system you will be using.**

## 1. PRE-TREATMENT CONSIDERATIONS

### 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.

### 3. ANESTHESIA

Use a topical preparation, as needed, to alleviate discomfort for sensitive patients or sensitive areas prior to treatment. Remove before treatment with mild soap and water or an alcohol swab, then plain water. Dry the area thoroughly before treatment. Topical anesthesia may have little effect on deeper treatments in most people and may be unnecessary.

### 4. HANDPIECE CLEANING

Prior to each treatment, clean the cooling plate with an alcohol swab. Check cooling plate during long procedures and clean as necessary.

### 5. EYE PROTECTION

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

***CAUTION: Tattooed areas should not be treated. Tattoo ink may absorb laser energy resulting in a color change in tattoo ink or a risk of epidermal damage.***

## 6. SETTING TREATMENT PARAMETERS

### 7. COOLING

#### 7.1.1. COOLING TEMPERATURE

12°C is recommended for maximum patient comfort. A coating of colorless gel, KY, surgilube may be used in conjunction with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin. The gel should be used as a very thin film on the bottom surface of the cooling plate.

***CAUTION: Check the cooling plate temperature prior to every treatment. The risk of epidermal injury such as blistering increases with decreased cooling.***

## 8. FLUENCE

Patient response can vary, so fluences should begin low and be increased gradually after assessing the individual patient response. The desired response is erythema within a few minutes of laser application. Reduce fluence by 20% over bony areas such as forehead.

**CAUTION: Excessive fluence or poor contact with skin can lead to dermal injury or blisters.**

## 9. PULSE WIDTH

Set the starting pulse width to 5 seconds.

Cooling Temperature	Starting Fluence	Pulse Width	Post Cooling	Passes
12°C	35 - 40 J/cm <sup>2</sup> < 20% on forehead	5 seconds	2 seconds	1 to 5

## 10. TECHNIQUE

### 11. PATIENT POSITION

It is usually easiest to lay the patient horizontally and stand directly behind the patient's head. Elevate the table so the patient's head is as high as the top of the BBL console.

Position the patient's head so the treatment area faces upward. Treat the area completely with one pass. Next, position the opposite side to face upward and complete one pass. For example: Treat the right temple completely with one pass. Reposition the patient's face. Treat the left temple.

### 12. TEST AREA

Treating a test area before a patient's first treatment can establish their response threshold and help establish safe starting parameters. For example: Begin by

testing the patient's forehead; then increase the fluence when progressing to the cheeks. Treatment requires lower fluence when treating over bony prominences.

A coating of colorless gel, KY, surgilube should be used in conjunction with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin. The gel should be used as a very thin film on the bottom surface of the cooling plate. Gel will insure contact in highly areas with highly irregular surfaces.

**IMPORTANT: Keep fluence below 40 J/cm<sup>2</sup> for the first treatment session, and monitor the patient for any evidence of prolonged erythema, swelling, urticaria or blistering.**

### 13. HANDPIECE POSITION

Position the patient so the HANDPIECE can be held perpendicular to the skin surface. Move the patient's head if necessary so that the treatment area is easy to reach.

Position the HANDPIECE so the cooling plate is in full contact with the skin. For highly curved regions use a smaller spot BBL adapter or push the skin upward with your other hand to contact the cooling plate to insure proper cooling.

The HANDPIECE must remain in contact with skin long enough (several seconds) to cool the surface of the skin. It will take several seconds for the deeper heat to propagate to the surface. A coating of gel, KY, surgilube should be used in conjunction with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin.

### 14. TREATMENT METHOD

Match the "trailing edge" of the next treatment to the "leading edge" of the previous treatment area. Do not overlap treatment spots. Perform up to 3 complete passes.

Make certain to maintain complete skin contact below the treatment area before, during and after the treatment. A coating of colorless gel, KY, surgilube may be used in conjunction with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin. Gel will insure contact in areas with highly irregular surfaces.

***CAUTION: Do not stack pulses. Repeated pulses in the same location may lead to a build up of subsurface heat and a subsequent blister or burn.***

**IMPORTANT:** Blistering is an indication of over treatment due to excessive temperatures, which can be caused by improper handpiece placement, overlapping or stacking pulses, improper cooling temperatures, or excessive fluence.

## **15. TREATMENT GOALS**

The immediate goal is light, uniform erythema developing a few minutes after treatment. The longer-term treatment goal, after 3 to 6 months, is collagen remodeling of partially denatured and contracted collagen resulting in subsequent rhytid improvement and reduction of laxity, followed by continued or maintained improvement with a maintenance program. Patients will typically report feeling tighter skin following treatment.

## **16. POST-TREATMENT CONSIDERATIONS**

### **17. OBSERVATIONS**

Erythema, a moderate sunburn sensation, and tightening should be noticed in the treatment area for up to two hours after treatment. Patients should not feel any significant discomfort after BBL/ST treatment.

### **18. INTERVENTION**

While not often used, cold compress can provide some comfort after treatment. If blistering occurs, aggressive wound treatment should be administered, i.e. Vigilon, Second Skin, silastic sheeting or other intervention.

### **19. INTERVAL**

Recommended time interval between treatments is 2- 4 weeks. Dermal changes from fibroblast activity may begin to be observed between 3 to 6 months after treatment. Incremental improvement may progress for six months or longer. Tightness of the treated area may be noticed immediately after treatment.

## **20. CONCURRENT PROCEDURES**

**COMBINATIONS – PROFILE** Rejuvenation treatments may be given in combination with other minimally invasive therapies. If a patient is to receive another treatment (light chemical peel, microdermabrasion, Botox, collagen injection) in conjunction with the BBL, it is advisable to perform the BBL treatment first. There may be increased sensitivity in the treated areas for an hour or two.

## **21. CONCLUSIONS**

Do not be overly aggressive. Begin conservatively and be patient. Results are determined by the physiology of the patient's skin. This is not a surgical process; collagen remodeling takes time. You should help your patient understand that the results are long term.

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## SAFE START PROTOCOL

### 1. Pre-Treatment:

- Clean area to be treated
- Anesthesia - Use a topical preparation if necessary. Remove before treatment.
- Clean hand piece prior to each treatment
- **Eye Protection - Always use eye protection for the patient, the operator and anyone in the laser treatment room**
- Set Cooling Plate Temperature
- Test fire at moderate fluence

### 2. Treatment:

- Set Cooling Temperature: 12°C is recommended.
- Set Fluence for TEST AREA, 40 j/cm<sup>2</sup>
- Check Cooling Temperature before each area to be treated

Cooling Temperature	Starting Fluence	Pulse Width	Post Cooling	Passes
12°C	35 - 40 J/cm <sup>2</sup> < 20% on forehead	5 seconds	2 seconds	1 to 5

- Treat with non-overlapping pulses
- POSITION HANDPIECE COOLING PLATE in full contact with treated area. Use a thin film of colorless gel, KY, surgilube with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin. Gel will insure contact in areas with highly irregular surfaces.
- ALLOW SEVERAL SECONDS OF COOLING before depressing laser foot switch.

### 3. Post-Treatment:

- OBSERVATIONS - Erythema for up to two hours after treatment.
- INTERVENTION - Cool compresses or ice packs can provide some comfort after treatment. If blistering occurs, aggressive wound treatment should be administered.
- INTERVAL - between PROFILE treatments is approximately 2 – 4 weeks.



#### 4. Perform treatment before Concurrent Procedures

**IMPORTANT:** The handpiece must remain in contact with skin long enough (several seconds) to cool the surface of the skin. It may take several seconds for the deeper heat to propagate to the surface. Make sure that the cooling plate is in good contact with skin.

#### **CAUTION**

*Tattooed areas should not be treated. Tattoo ink may absorb laser energy resulting in a color change in tattoo ink or a risk of epidermal damage.*

*The risk of epidermal injury such as blistering increases with decreased cooling. Check the cooling plate temperature prior to every treatment. Clean the cooling plate with a soft cotton gauze moistened with alcohol before every treatment.*

*Overlapping pulses may lead to excessive subsurface temperature resulting in blisters or denatured collagen. Proper pulse spacing will avoid this.*

*Do not stack pulses. Repeated pulses in the same location may lead to a build up of subsurface heat and a subsequent blister or burn. Use multiple passes completely treating an area before doing a subsequent pass.*