TREATMENT GUIDELINES
Pearl Fractional Treatment Guidelines

The following guidelines are based on practitioner feedback for treatments with the Pearl Fractional laser system on patients with Fitzpatrick skin types I-IV. Additional treatment information is discussed in the Pearl Fractional Clinical Training CD included with the system.

The Pearl Fractional laser system should only be operated by qualified practitioners who have received appropriate training and have thoroughly read the operator manual.

Consult the Operator Manual for additional information, including contraindications, expected transient events and possible adverse effects.

PATIENT CARE CONSIDERATIONS:
It is important to be aware that patients are more susceptible to irritation or infection following procedures that disrupt the surface of the skin. If this occurs, it is important to properly diagnose and treat these conditions in order to avoid delayed wound healing, scarring, or spread of an infection. Treatment for these conditions often requires prescriptive medications.

During the first 3 or 4 days after treatment, the skin will be more susceptible to irritation which can lead to contact dermatitis which can be caused by substances that do not normally irritate the skin. It is important for the patient to avoid putting anything in contact with their skin other than those items specifically recommended for post-treatment care, and to always thoroughly wash hands prior to touching the treated area.

It is possible for a treatment to activate the herpes simplex virus in the treated area which may lead to scarring. Because not all carriers of the herpes simplex virus are aware that they have the virus, many physicians provide prophylactic antiviral medications to all patients prior to receiving an ablative treatment. Prophylactic treatment may not always eliminate the incidence of herpes activation. It is important to watch for, and treat, any post-treatment activation.

The skin is more susceptible to bacterial and fungal infections after disruption from an ablative procedure. The probability of these infections occurring can be reduced by good post-treatment skin care.

A persistent grid pattern may be apparent on the treated skin and usually resolves with time. In rare cases, it may be permanent.

Patient should contact the treating office if they experience symptoms such as increased pain, drainage, increased itching, severe redness or fever, the appearance of pustules, a cold sore or a similar tingling sensation, or any other sign that healing is not proceeding normally.

This information is intended to provide awareness of these issues, but is in no way complete. Additional information on possible irritation and infection following ablative laser treatments, and their care, is contained in the medical literature. One such source is the chapter entitled “Complications in Laser and Light Surgery” by Tina S. Alster and Elizabeth L. Tanzi, in the book “Laser and Lights, Volume 2”, edited by David J. Goldberg, of the series “Procedures in Cosmetic Dermatology”, edited by Jeffrey S. Dover. This book was published in 2005 by Elsevier Saunders.
PRE-OPERATIVE

- Conduct a patient consultation complete with medical history prior to treatment and prescribe any pre-op medications.

- Pigmented lesions should be evaluated for potential skin cancer prior to treatment. If these are present, the lesion should not be treated unless diagnosed as benign.

- Set the patient’s expectations with regards to an average of 5 – 7 days social downtime.

- Clean the skin, including removal of all make-up and other skin care products. Any creams or products left on the skin will interfere with the light and may cause irregular results and unwanted side-effects.

- Hair in the treatment area should be closely shaven prior to treatment.

- Pre-operative photographs should be taken with consistent technique (patient positioning, camera settings, and room lighting) prior to the initial treatment for general reference. Printed pre-operative photos can also be used to compare and duplicate the same patient position when taking follow-up photos.

- A topical anesthetic is recommended for this procedure. Additional forms of pain management are often used to assist in patient comfort. CAUTION: Toxicity may result with the overuse of topical anesthesia. Consult the manufacturer’s labeling.

- Remove anesthetic completely prior to treatment.

- Wipe the skin with alcohol. Allow the skin to dry before treating with the laser. Any residual anesthetic will absorb light and may cause irregular results or unwanted side effects.

SUPPLIES & MATERIALS

- Smoke Evacuator
  - Change the tubing and filters as per the manufacturer’s recommendations
- Laser plume masks - filters to 0.1μm (optional)
- Isopropyl Alcohol
- Gauze pads
- Tongue depressors
- Gloves
- Topical anesthetic
  - Additional forms of pain management may also be used to assist in patient comfort
- Occlusive ointment (e.g. plain Vaseline or Aquaphor ointment)
- Safety eyewear must be worn by ALL people in the treatment room
  - The patient should be given the solid, light blocking eyewear provided by Cutera.
  - Operator Goggles - Optical Density (OD) of 2.5 or greater at 2790 nm
PEARL FRACTIONAL TREATMENT PARAMETERS FOR SKIN TYPES I-IV*

Specific parameters are provided as a guide only. Patient response will vary.

<table>
<thead>
<tr>
<th>Treatment Area</th>
<th>Energy</th>
<th>Density</th>
<th>Passes</th>
<th>Energy</th>
<th>Density</th>
<th>Passes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheeks/Forehead</td>
<td>80mJ - 160mJ</td>
<td>2-3</td>
<td>2-3</td>
<td>60mJ - 120mJ*</td>
<td>1-2</td>
<td>1-2</td>
</tr>
<tr>
<td>Perioral/Nose Deep Imperfections</td>
<td>120mJ – 160mJ</td>
<td>2-3</td>
<td>2-3</td>
<td>80mJ - 120mJ*</td>
<td>1-2</td>
<td>1-2</td>
</tr>
<tr>
<td>Upper / Lower eyelids Periorbital</td>
<td>60mJ - 160mJ</td>
<td>1-3</td>
<td>2</td>
<td>60mJ - 120mJ*</td>
<td>1-2</td>
<td>1-2</td>
</tr>
<tr>
<td></td>
<td>80mJ - 160mJ</td>
<td>1-3</td>
<td>2</td>
<td>60mJ - 120mJ*</td>
<td>1-2</td>
<td>1-2</td>
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</table>

*For Skin Type 4, for the first pass, recommend using 60mJ-80mJ over the entire area. For the second pass, recommend using 120mJ for individual deeper imperfections only.

Exceeding the recommended density, energy and/or number of passes may result in complications such as scarring and permanent hypopigmentation.

Skin Types I-III - Minimum of 2 passes is recommended for randomization and a more uniform treatment. If higher density is used for the first pass, lowering the density for subsequent passes may help with pain control.

Skin Type IV - Higher risk of Post Inflammatory Hyperpigmentation (PIH). Start with lower energy and 1 pass to decrease risk unwanted side effects (2nd pass on problem areas only). Use of a bleaching agent may decrease risk of PIH.

Off the Face & Skin Types V-VI - Parameters have not yet been developed. These treatments may increase the risk of unwanted complications and side effects and healing time may be prolonged.

1. **Energy** determines the total depth of tissue that is removed with the treatment. While this will vary from person to person, an energy of 160mJ has been found to remove approximately 400 to 800 microns of tissue per micro-spot and an energy of 240mJ has been found to remove approximately 600 to 1000 microns of tissue per micro-spot.
   - Higher settings will result in a deeper treatment and may increase the risk of side effects or complications, such as prolonged healing, scarring and permanent hypopigmentation.

2. **Delay** determines the time between the delivery of scan patterns if the footswitch is maintained in the down position. Delay times of 1 to 2 seconds are typically used, with longer delay times for larger patterns.

3. **Density** specifies the number of micro-spots within a scan pattern. Density 1-3 is recommended while performing a 2+ pass procedure, which will result in a more consistent, blended appearance.
   - Density 4 and 5 cover more area and increase the risk of side effects or complications, such as prolonged healing, scarring and permanent hypopigmentation.
   - Density is calculated using total treated area (ablation + coagulation)

<table>
<thead>
<tr>
<th>Density 1</th>
<th>Density 2</th>
<th>Density 3</th>
<th>Density 4</th>
<th>Density 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>4%</td>
<td>8%</td>
<td>12%</td>
<td>16%</td>
<td>32%</td>
</tr>
</tbody>
</table>

4. **Scan Pattern** determines the location of the delivery of the 300 microns diameter micro-spots. Selection options will be discussed under Recommended Technique. The size of the scan pattern can be varied during treatment. The aiming beam will indicate where the scan pattern will begin and end.
RECOMMENDED TECHNIQUE:

- Always use protective eyewear. Laser safe eyewear is required for everyone in the room at all times.
  - Operator Goggles - Optical Density (OD) of 2.5 or greater at 2790 nm
  - The patient should be given the solid, light blocking eyewear provided by Cutera.
    - Internal laser safe eye shields should be used anytime the eyelids are being treated.

- A smoke evacuator is recommended for all Pearl Fractional treatments to reduce airborne contaminants as part of universal precautions.
  - The smoke evacuator hose should be attached to the snorkel handpiece and suction set high enough to capture the airborne particles and prevent plume odor.
  - Laser plume masks are optional (filters to 0.1 μm).

- Choose the energy, density, and delay as per the PEARL FRACTIONAL TREATMENT PARAMETERS section of this document.

- Hold the handpiece perpendicular to the skin with the stand-off in contact with the skin. The stand-off indicates the optimal distance from the laser to the skin being treated. The aiming beam will indicate the area to be treated. Note: it is important to maintain gentle contact with the skin as pressing the stand-off into the skin will change the focal distance and may result in an over treatment. Do not pull the handpiece away during the scan pattern.

- A test pattern can be delivered on a tongue depressor to verify laser performance and familiarize the patient with the sound of the laser prior to treatment.

- Depress and hold the foot pedal down while holding the handpiece in place until the scan pattern is complete.

- Once the scan is complete, move the handpiece to the next treatment location. Using the aiming beam as a guide, place the scan pattern adjacent to any previous scans with a slight overlap, and repeat.

- Gauze or paper products should be moistened with water to prevent a fire hazard.

- Avoid treating the hairline and eyebrow area as the hair will singe.

- Do not treat over areas with tattoos including permanent make-up.

- Periodically check the lens for debris and clean as appropriate.

- Pinpoint bleeding may occur during treatment. It can easily be controlled with manual pressure.

- Do not wipe post-treatment or between passes.

- For the second pass, the handpiece should be rotated 30° from the first scan pattern and move in a line at an angle to the first pass. For the third pass, the handpiece should be rotated 30° in the opposite direction from the first scan pattern. This technique is recommended to randomize delivery of micro-spots, increase patient comfort and improve treatment coverage.

- If intraocular lenses are used, the periorbital area may be treated first to minimize skin hydration due to tear production.
POST-OPERATIVE:

- Immediately after treatment apply a thin layer of occlusive ointment. Examples include, but are not limited to plain Vaseline or Aquaphor Healing Ointment. Reapply as needed to maintain a thin continuous layer for 3-7 days.
  - Topical antibiotics (e.g. Neosporin, Polysporin or Bacitracin) are common sources for contact dermatitis and should be avoided.

- Provide and review the Pearl Fractional Post Care Instructions and Pearl Fractional Treatment Progression with the patient. An example of the post-treatment instructions is provided on the Pearl Fractional Clinical Training CD and online on the Cutera customer Education website at www.cutera.com/education.

- Pinpoint bleeding may increase and continue after treatment. This usually resolves within 24 hours.

- Erythema is a normal reaction to treatment. More aggressive treatments may result in longer lasting erythema which resolves with time.

- Edema (swelling) may occur in some patients. While this is temporary, sleeping with the head elevated may help to minimize this.

- Some patients experience a burning sensation immediately after treatment. This usually resolves within 1 hour after application of the occlusive ointment.

- Re-epithelialization occurs within 5-7 days after treatment for most patients. Make-up can then be applied.

- Remind patient to avoid sun exposure post-treatment.

- Replace the stand-off after each patient procedure to prevent blood and body fluid cross-contamination between patients. Dispose of a used stand-off using standard biohazard procedures. The stand-off cannot be autoclaved.

- Between each patient, the entire hand piece, including the circular clamp that holds the stand-off in place and the umbilical cord, must be cleaned thoroughly using germicidal wipes that are antibacterial, antifungal, antiviral (e.g. SaniCloth or PDI).

- The smoke evacuator snorkel can be detached from the handpiece and cleaned with 1 part bleach & 10 parts water in the following manner;
  1) Place the soiled snorkel in a small wash basin containing 1:10 solution of bleach and water ensuring it can be completely submerged.
  2) Using a small, non-abrasive, flexible brush or pipe cleaner to gently scrub the inner wall of the snorkel.
  3) Using a sponge or gauze pad gently clean the exterior of the snorkel.
  4) After cleaning, rinse the inner and outer surfaces of the snorkel thoroughly with water.
  5) Air-dry the entire piece by gently shaking it.

  **NOTE:** Cleaning procedure should be clearly understood before proceeding using manufacturer’s recommendations. In addition the operator should follow any and all internal procedures regarding the handling of bio hazardous material and the use of personal protection equipment.

  **NOTE:** To loosen dried-on debris, you may also pour the 1:10 solution through the inner snorkel or submerge and soak the snorkel in the solution for approximately 10 minutes.

  **CAUTION:** Do not use harsh chemicals that may damage the snorkel, such as acetone.

- Replace smoke evacuator filters and tubing per manufacturer’s recommendations and guidelines

- If repeat treatments are performed, the recommended interval is 4 weeks or longer.
Fitzpatrick Classification Questionnaire

<table>
<thead>
<tr>
<th>SCORE</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the natural color of your hair?</td>
<td>Sandy red</td>
<td>Blond</td>
<td>Chestnut, dark blond</td>
<td>Dark brown</td>
<td>Black</td>
</tr>
<tr>
<td>What is the eye color?</td>
<td>Light blue, Gray, Green</td>
<td>Blue, Gray, Green</td>
<td>Blue</td>
<td>Dark Brown</td>
<td>Brownish Black</td>
</tr>
<tr>
<td>What is the color of sun unexposed skin areas?</td>
<td>Reddish</td>
<td>Very pale</td>
<td>Pale with beige tint</td>
<td>Light brown</td>
<td>Dark brown</td>
</tr>
<tr>
<td>How many freckles on unexposed skin areas?</td>
<td>Many</td>
<td>Several</td>
<td>Few</td>
<td>Incidental</td>
<td>None</td>
</tr>
<tr>
<td>What happens when you are in the sun TOO long without sunblock?</td>
<td>Painful redness, blistering, peeling</td>
<td>Blistering followed by peeling</td>
<td>Burns, sometimes followed by peeling</td>
<td>Rarely burns</td>
<td>Never had a problem</td>
</tr>
<tr>
<td>How well do you turn brown?</td>
<td>Hardly or not at all</td>
<td>Light color tan</td>
<td>Reasonable tan</td>
<td>Tan very easily</td>
<td>Turn dark very quickly</td>
</tr>
<tr>
<td>Do you turn brown within one day of sun exposure?</td>
<td>Never</td>
<td>Seldom</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>How does your face respond to the sun?</td>
<td>Very sensitive</td>
<td>Sensitive</td>
<td>Normal</td>
<td>Very resistant</td>
<td>Never had a problem</td>
</tr>
<tr>
<td>When did you last expose yourself to the sun or artificial sun treatments?</td>
<td>More than 3 months ago</td>
<td>2-3 months ago</td>
<td>1-2 months ago</td>
<td>Less than 1 month ago</td>
<td>Less than 2 weeks ago</td>
</tr>
<tr>
<td>Do you expose the area to be treated to the sun?</td>
<td>Never</td>
<td>Hardly ever</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
</tbody>
</table>

- **00-07 points = Skin type I**
- **08-16 points = Skin type II**
- **17-25 points = Skin type III**
- **25-30 points = Skin type IV**
- **30-40 points = Skin type V & VI**