

### A. Description

DC International Pearly White Smile (PWS) bleaching gel is a dental whitening gel used in combination with Diode laser systems with a wavelength from 810nm to 980 nm and an ND:YAG Laser with a wavelength of 1064 nm. The laser activates the PWS whitening gel through a specialized hand piece. The whitening gel is designed to work with Diode and ND:YAG laser systems with bleaching function.

It is advised that PWS bleaching gel is only used by dental professionals and skilled office staff and they must review this entire document before starting the whitening procedure.

### B. Indications

The diode and ND:YAG laser systems are designed to be administered only by the dental professional for partial and full-arch whitening procedures. PWS bleaching gel may be used in cases where one or several teeth are desired to be lightened. It is designed to be safe and effective, and is an excellent means to bleach and whiten dark, yellowed, or discolored teeth with extrinsic and intrinsic staining. A dental cleaning (non-glycerine based) and prophylaxis is recommended to remove any plaque and stain before the PWS bleaching gel whitening procedure. The degree of whitening varies from patient to patient based on the type of stain, enamel thickness, tooth structure and age. Typical results range from six to twelve shades on the Vita Shade Guide Brightness Scale. Teeth with deep, intrinsic stain in the grayer tones generally will not respond as well as yellow shaded teeth.

The dentist is encouraged to discuss predictability and efficacy with the patient prior to the start of the whitening process to establish realistic expectations on the part of the patient.

### C. Contraindications

Patients with periodontal disease, exposed root surfaces, damaged or fissured enamel, gross caries, allergies to chemical products such as hydrogen peroxide, or other similar conditions are not candidates for laser tooth whitening procedures

**NOTE:** Doctors should perform a complete intra-oral exam before the whitening procedure. Make sure the patient has already had a consultation and has realistic expectations of the procedure.

### D. PWS bleaching gel Treatment Order

- 1) Prepare the laser system do to regulations of the user handbook and activate the laser to ensure laser is operating correctly.
- 2.) Ensure that you have everything required to perform the whitening treatment
- 3.) Do not mix the PWS and hydrogen peroxide until the patient arrives.
- 4.) Make sure you have established a communication method with the patient before starting the procedure.
- 5.) Ensure vitamin E is on hand and ready to be used with cotton buds.
- 6.) Measure and record the shade of the patient's teeth using a Vita Shade guide. Use the brightness scale as shown below

### BRIGHTNESS SCALE

**B1-A1-B2-D2-A2-C1-C2-D4-A3-D3-B3-A3.5-B4-C3-A4-C4**

- 7.) Ensure that the patient is wearing laser goggles at all times during the treatment and that the goggles fit tightly around their nose. If not, place gauze appropriately to fill the gap.
- 8.) Have tissues on hand to wipe applicators and spatulas if necessary.
- 9.) Place the bite block and cheek retractor in the patient's mouth prior to commencing the whitening treatment and apply Vaseline to the lips to keep any soft tissue away from the teeth. Cotton rolls are recommended for increased protection and patient comfort. Do not pumice the teeth until the bite block and cheek retractor are in place.
- 10.) Clean teeth surfaces using a pumice that does not contain glycerin. Try to remove any dental plaque and superficial stains.
- 11.) Rinse and air dry the teeth and especially the gums around the teeth to be whitened to avoid leakage of the PWS Gel under the liquid dam during the whitening treatment. Ensure that the teeth are dry before each application of PWS gel.
- 12.) Open the hydrogen peroxide carefully by cutting the top and put everything in the PWS powder container. Stir until the desired consistency is achieved.
- 13.) Apply PWS Liquid Dam onto the gingiva:

### PWS Liquid Dam Isolation Procedure

- 13a) Remove cap and attach syringe tip securely onto Gingival Barrier syringe.
- 13b) Express Gingival Barrier to build a 4-6 mm by 1.5-2 mm thick strip onto gingiva. Lap approximately 0.5mm onto enamel. If excess resin flows onto enamel, secure area with curing light and use a hand instrument to trim back excess. Extend resin beyond the last tooth to be bleached. Where open embrasure(s) exist, express resin through the opening onto lingual, filling embrasure space completely. This will protect interdental papilla and lingual gingival tissue.
- 13c) After Gingival Barrier is applied, cure resin with a quality curing light 20 seconds per light guide width. Clean teeth with prophyl paste to remove any excess resin film. Use caution not to dislodge cured Gingival Barrier.
- 13d) Vaseline can also be applied onto the mucosa in areas which have not been protected with liquid dam.

**WARNING: Do not perform this procedure without gingival protection.**

- 14.) Apply a thin layer of PWS whitening gel over all teeth to be whitened. The gel should be evenly spread over teeth (do not push up to dam) to about 1,5 mm thickness.

**NOTE:** During the procedure, pay close attention to ensure that the gel does not contact patient's gingiva, tongue or lip. Take adequate precaution to ensure that patient does not swallow any gel.

**NOTE:** If patient experiences tooth sensitivity during this procedure, stop the procedure and , evaluate the patient's condition. **DO NOT** proceed if the sensitivity continues.

- 15.) In one in-office visit, the doctor can perform a maximum of four (4) Gel Applications on one patient, known as session
- 16.) Lase teeth following the instructions of user manual from the laser
- 16a.) Please leave gel after laser activation at least 4 minutes on teeth
- 17.) Suck gel using high-speed suction, and then flush with an air and water spray to remove any residual gel. If the patient's teeth could whiten further, a second and third application of gel may be used at the clinician's discretion. Perform steps 14 through 17.
- 18.) Repeat steps 7 to 12 if necessary up to two times
- 19.) After the sessions are completed, wipe the teeth with gauze and rinse well with water.
- 20.) Remove the Liquid Dam by sliding the tip of an explorer or forceps between the gingiva and the barrier. Lift it away carefully. Check interproximally for any debris. Use an explorer or floss. Rinse again.
- 21.) A final polish can be performed with PWS desensitizing gel to give a luster and shine to the teeth.

- 22.) Remove bite block
- 23.) Measure the shades using the Vita Shade Guide Brightness Scale. Compare initial shades with final shades, and discuss the outcomes with the patient.
- 24.) Remove cheek retractor

**NOTE:** Optionally, vitamin E can be applied to irritated soft tissue at the end of the procedure. If additional whitening is necessary, the clinician can schedule a new appointment in two weeks.

### E. Precautions & Warnings

- It is required that laser protective eye wear is worn by the patient and any dental personnel in the operatory during the procedure. Office personnel who do not have any protective eye wear should not enter the operatory while the laser system is in use. The protective eye wear received with the system is specific to the laser's wavelength and also protects the operator, patient and any dental auxiliary personnel from inadvertent contamination of their eyes with the whitening gel.

- Protective gloves must be used throughout the whitening procedure. It should be noted that the whitening material, when in contact with mucosal membranes, or unprotected epidermis, can be caustic and cause irritation and burning. If at any time during the procedure the patient experiences discomfort or burning, stop the procedure. Irrigate the area with copious quantities of water, and evacuate excess water with the high-speed suction. **DO NOT** proceed if the patient continues to

experience discomfort, burning sensations or any other sensations that are uncomfortable to the patient. Apply Vitamin E to areas where soft tissue has been irritated by the gel.

- Patient expectations must be discussed prior to the start of the whitening process. It is recommended to evaluate tooth shade prior to the procedure, and again at the conclusion of the treatment. Though it is possible to apply the **PWS** whitening gel for three (3) applications (cycles) per patient visit, the desired results may be achieved in one or two applications.

- Patients' medical histories must be carefully evaluated for conditions such as allergies to hydrogen peroxide or other oxidizing agents, heart disease, lung disease, bleeding disorders, or immune system deficiencies. **PWS** bleaching gel should **NOT** be used on any patient with known allergies to hydrogen peroxide, resin-based materials or other such chemicals. Medical clearance from the patient's physician is advisable when doubt exists regarding treatment.

- Do not use **PWS** Liquid Dam on patients with known sensitivity to resin. It is advisable to test Liquid Dam on a small section of the patient's gum, before attempting this procedure.

- When curing the **PWS** Liquid Dam, hold the curing light at least 2 cm away from the resin to reduce any heat-induced sensitivity during curing.

- Application on the teeth must be uniform and free from gaps to ensure uniform whitening of teeth surfaces. Monitor patient's progress during treatment, and discontinue use if patient reports

sensitivity or discomfort, or if clinical results exceed desired effects for patient and operator.

- **DO NOT** anesthetize the teeth for this procedure. If any sensitivity occurs, discontinue the process as stated above. Caution must be exercised regarding the inadvertent transferal of whitening gel from gloved hands or dental equipment onto non-target tissues. Copious irrigation with water is recommended when this occurs.

- Restorations must be intact, and areas of exposed dentin must be treated prior to the start of whitening.

- A rebound effect of tooth shade could occur. It is recommended to wait two weeks prior to placement of proximal restorations, since stabilization of tooth shade may take several days to two weeks after the treatment. The patient may experience positive (lighter) or negative (darker) rebound after this procedure is completed for up to two weeks.

- Existing crowns, inlays, veneers, and composite restorations will not change color due to this whitening process. The patient and dental professional should discuss possible cosmetic implications that existing restorations pose in whitening cases.

- Areas of hypo calcification will bleach faster than adjacent tooth structure. These are not always clinically evident at the onset of whitening, and when visible, the gel should be placed carefully adjacent to these areas to blend the remaining surface shade.

- The patient should be advised not to consume products

that stain teeth up to 48 hours after treatment. This would include, but not be limited to, some fruits, coffee, red wine, tomato sauces, tea, tobacco, etc.

- It is **NOT** recommended to use **PWS** on those who are pregnant or nursing.

- Since **PWS** whitening gel is an oxidizing agent, and oxidizing agents have been reported to potentiate the action of some carcinogens, it is recommended that patients discontinue the use of tobacco and alcohol containing products prior to the use of this whitening system and during any part of the whitening procedure.

- If you see any periapical areas of pathology (PAT), you should be aware of that condition.

- Keep whitening gel out of the reach of children. Ensure that whitening gel is not accessible by children or unqualified personnel.

The **PWS** gel is designed only for use with all Diode Laser systems from 810nm to 980nm and an ND:YAG Laser with a wavelength of 1064 nm. **DO NOT** use this gel with any other laser systems, or light sources. **PWS** gel when used with other lasers or light sources may result in damage to the light source and adverse effects to the patient.

### Tooth Sensitivity

To reduce or prevent tooth sensitivity during and/or after the **PWS** whitening procedure, the dentist may recommend appropriate pain relief medication 30 - 60 minutes prior to the procedure and postoperatively. The **PWS** desensitizing gel may also be recommended for post-treatment tooth sensitivity relief.

### CAUTION!

Read Instructions before Treating Patients!  
For Professional Use Only.  
Avoid Any Eye and Skin Contact. Rinse Thoroughly with Water if Exposed. |  
Keep Out of Reach of Children  
Not for Injection  
Destroy After Use  
Strong Oxidizing Agent

### Shelf Life:

6 months unrefrigerated,  
12 months refrigerated

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Revisionsnumber 1.02 Revisionsdate 10.10.2009 0482



## Pearly White Smile Laser Tooth Whitening Gel

### This kit contains:

- 1 Container with pre-dosed **PWS** Power Bleaching Powder
- 9 ml H2O2 30% basic solution
- 1 Syringe of **PWS** Desensitizing Gel
- 1 Syringe of **PWS** Liquid Dam
- 1 Tip for Liquid Dam Syringe
- 1 Tip for Desensitizing Gel Syringe

### TO REORDER PLEASE CALL

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