

PERIODONTITIS/GINGIVITIS TREATMENT PROTOCOL



ABOUT PERIOWAVE™

The Periowave™ Photodisinfection System is a non-thermal laser based antimicrobial system intended for the treatment of periodontal disease. It is indicated for use in adults as part of a periodontal health maintenance program, which should also include scaling and root planing (SRP).

Periowave™ significantly enhances the outcome of SRP and accelerates the healing process. SRP physically removes calculus and plaque; Periowave™ destroys the bacterial biofilm and virulence factors left behind by the mechanical debridement process.

Periowave™ is safe for both human tissue and dental materials. Because Periowave™ utilizes cold laser light for activation of the sensitizing solution, there is no risk of thermal damage to patient tissues, prosthetics or implants. By comparison, subgingival curettage by thermal lasers can damage root surfaces, carbonize soft tissues (thereby inhibiting junctional epithelium reattachment) and overheat implant materials, risking osseous deintegration.

PROTOCOL STATEMENT

Periowave™ has been thoroughly tested in 5 separate clinical studies ranging from 12 weeks to 1 year of follow-up, with over 20,000 defect sites treated. All trials were randomized, prospective, examiner-blinded, parallel-group studies evaluating Periowave™ in combination with SRP against SRP alone in the treatment of adults with chronic periodontitis. Since launch in 2006, over 100,000 Periowave treatments have been administered without any serious adverse events associated with the therapy. The unique protocol detailed below is the result of careful analysis of feedback from researchers and clinicians, and is intended to provide the best possible clinical efficacy. Periowave™ is ideally suited for treatment of 4+ mm pockets that bleed on probing. Periowave™ is also appropriate for use in patients presenting with gingivitis. Periowave™ should be used following thorough SRP, once post-instrumentation bleeding has been controlled. Successive (recall) treatments may benefit from light manual and/or ultrasonic debridement prior to treatment. Each defect is treated individually, and it is important to check the contralateral side of the tooth, especially at interproximals, as these sites may benefit from additional photodisinfection. Patients should be re-treated as early as possible, optimally one to four weeks after initial treatment. Long-term results can be significantly enhanced by a follow-up treatment 3-6 weeks after the first treatment and at regular recall intervals. Clinical outcomes include significant reduction in pocket depth, increase in clinical attachment level, decrease in bleeding on probing and improved gingival tone and texture over SRP alone.

GUIDELINES FOR OPTIMAL RESULTS WITH PERIOWAVE™

(follow the Directions For Use for full operating details and laser safety instructions)

1. IDENTIFYING TREATMENT SITES

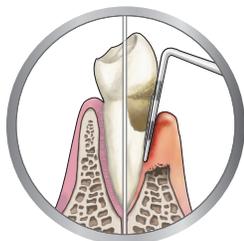
- Proper diagnostic probing (Figure 1) at six sites around each tooth is crucial to identify periodontal defects. Pocket depth, recession and bleeding on probing should be monitored during and after therapy.
- All sites 4+ mm around a tooth/implant that bleed on probing or suppurate are candidates for Periowave™ photodisinfection therapy.
- Carefully evaluate sites adjacent to the defect for separate treatment requirements (e.g. interproximal and furcation sites).

Defect sites left untreated can compromise the healing effect of Periowave™.

RECOMMENDATIONS FOR TREATMENT

1. Identify and document treatment sites
2. Thoroughly debride affected teeth and/or implants
3. Minimize bleeding
4. Irrigate each treatment site
5. Illuminate each treatment site
6. Clean and disinfect the Laser Insert, sterilize the Outer Sheath
7. Retreat as necessary at recall.

HEALTHY



PERIODONTAL DISEASE

Figure 1

2. THOROUGH PERIODONTAL DEBRIDEMENT (SRP) OF THE AFFECTED TOOTH IS NEEDED AT INITIAL TREATMENT

- Thorough debridement leads to better and more consistent results and is required prior to initial photodisinfection procedure



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to remove the layers of subgingival calculus that impede soft tissue reattachment and provide a safe harbor for oral bacteria.

b. To minimize bleeding and to maximize outcomes, instrumentation is best accomplished with thorough ultrasonic instrumentation and specialized curettes and files to finish.

3. HEAVY BLEEDING AFTER SRP MUST BE MINIMIZED BEFORE BEGINNING PERIOWAVE™ TREATMENTS

a. Heavy bleeding after SRP may prematurely flush the photosensitizer out of the pockets, thereby reducing treatment effectiveness.

b. Light direct pressure with a damp gauze pad is usually enough to control bleeding prior to Periowave™ treatment.

c. If profuse bleeding cannot be controlled, a follow-up appointment may be necessary to perform the Periowave™ treatment. Periowave™ treatment may still be performed in cases of light bleeding. Bleeding is likely to subside after illumination.

4. PERIOWAVE™ IS A 2-STEP PROCESS: IRRIGATION & ILLUMINATION

a. Each defect site requires placement of photosensitizer (irrigation step) immediately followed by 60 seconds of laser light activation (illumination step). For example, three sites around a tooth require three separate cycles of irrigation and illumination.

b. Treat one defect site at a time. Each treatment site must be irrigated and illuminated before the next defect site is irrigated and illuminated.

c. Use of the laser without the photosensitizer, or vice versa, will not produce results. Do not use the photosensitizer with other light sources; the photosensitizer requires a specific red wavelength to be properly activated.

5. IRRIGATION TECHNIQUES

a. Attach the irrigating cannula to the syringe. Carefully dispense a few drops of sensitizing solution to assure flow. Bend the cannula to facilitate access to the periodontal site.

b. Place the irrigation cannula at the apex (deepest point) of the pocket and slowly dispense the solution (figure 2).

c. Continue to irrigate the pocket until the solution can be seen flowing over the free gingival margin.

d. Too little solution may negatively affect the efficacy of treatment.

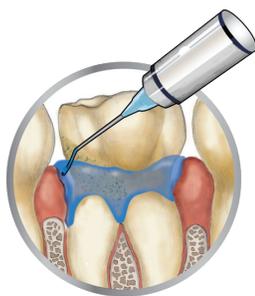


Figure 2: Irrigation

e. The 0.6 mL Periowave™ kit is designed to treat up to 3 defects; the 2.0 mL Periowave™ kit is designed to treat up to 10 defects. Complex defects may require more solution.

6. ILLUMINATION TECHNIQUES

a. Gently place the light diffusing tip into the apex of the irrigated treatment site and activate the laser (figure 3). Use caution and a light handed working stroke when inserting the light diffusing tip to the base of the sulcus.

b. If treatment causes bleeding, immediate retreatment of the site with Periowave™ may be needed to ensure desired effectiveness.

c. Ensure that the light diffusing tip remains at the bottom of the defect for the duration of the treatment time. Minor movement of the tip in the defect site during illumination is acceptable.

d. In very deep and wide defects, several illumination steps (2 to 4) may yield better results.

e. It is not necessary to suction or flush the solution from the gingival margin.

f. Gently wipe the light diffusing tip with damp gauze after each treatment to prevent accumulation of dried blood or dried photosensitizer. These deposits may cause an interruption of the laser light, resulting in reduced efficacy and possible deformation of the light diffusing tip.

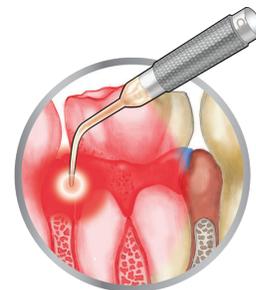


Figure 3: Illumination

7. OPTIMAL RE-TREATMENT INTERVAL

a. To reduce early biofilm rebound, patients should be re-treated as early as possible, optimally one to four weeks after initial treatment.

b. Pockets presenting with continued disease symptoms at any recall interval should be re-treated.

c. While SRP is not required prior to follow-up Periowave™ treatments, judgement should be used regarding the presenting plaque and calculus levels in order to determine whether light manual or ultrasonic debridement and lavage is indicated prior to treatment.

d. Full mouth evaluation and documentation should be carried out at the normal periodontal recall interval.

8. CLEAN AND DISINFECT THE PERIOWAVE™ SYSTEM

a. Follow instructions in the Periowave™ User Manual to clean and disinfect your device after each patient is treated.

b. For further clarification and assistance, please contact Periowave™ Customer Care or your Periowave™ representative.

