# Periowave Photodisinfection System

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<th>Received</th>
<th>Periodontal Therapy Periowave™ Photodisinfection System</th>
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<tr>
<td>11.10.08</td>
<td>Provisional Approval</td>
<td>03.26.09</td>
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<td>11.24.08</td>
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**Explanation of IAOMT position:** Thorough periodontal disinfection – well done SR

**Name of Scientific Review:** Periowave™ Photodisinfection System

**Alternative name(s) of Scientific Review:** Photodynamic Therapy for the Treatment of Periodontal Disease

**This Scientific Review is related to:** Dentistry and Medicine

**This Scientific Review is a:** Equipment and Procedure

**Purpose of the Scientific Review:** To facilitate the disinfection of periodontal pockets and initiate healing by eliminating many of the pathological microorganism species known to be causative in periodontal disease.

**Scientific Review History:** Lasers have been shown to be effective for killing all types of pathogens. With the subsequent development and use of photo-initiator chemicals or dyes to selectively target pathogens known to be associated with periodontal disease, products and procedures were developed that could effectively disinfect infected periodontal pocket sulcus sites without the use of heat. This non-heat process alleviates the potential for tissue damage and therefore the need for either anesthesia or post-operative wound healing while still maintaining effective microbial kill statistics.

This therapy, known as Photodynamic Therapy or PDT, employs a non-toxic dye, called a photosensitizer, and a low intensity visible light which, in the presence of oxygen, combine to produce cytotoxic species that are able to effectively kill all forms of microbes. Infections of the mouth are mostly localized in nature but if left untreated can lead to potentially life-threatening medical conditions. As most mouth infections are readily accessible to the products and procedures of PDT, they are therefore well suited to treatment by this modality. Applications of PDT in dentistry are growing rapidly for the treatment of oral cancer, bacterial and fungal infections, and the photodynamic diagnosis of the potential transformation of oral lesions. Periowave™ is a PDT system specifically designed and engineered for the treatment of periodontal infections and is certified for sale and use in Canada for this purpose.

**A brief description of the Scientific Review:** After the appropriate scaling and debridement of a patient, a proprietary photosensitizing solution is injected into an infected periodontal pocket site. The photosensitizing solution is able to selectively attach to targeted species of pathogens in the desired treatment area. A non-thermal diode laser attachment is then inserted into the pocket and illuminated for a 60 second interval to activate the solution. This photoactivation of the solution leads to the formation of reactive oxygen species which are able to break the cell walls structures of the targeted pathogens, and as in the case of the Periowave™ system, eliminate the pathogens associated with periodontal disease. This effectively disinfects the sulcus and or diseased periodontal pockets being treated, and promotes the successful healing of the affected surgical site.

**A specific description of this Scientific Review:** Biofilms play a very important and potentially destructive role in periodontal disease. They are structured communities of microorganisms that live within an encapsulated or
Photodisinfection procedures done in conjunction with scaling and root planning have been shown to statistically have significant improvements in post-operative healing success over the use of scaling and root planning alone. When used in combination with normal routine scaling and root planning procedures, photodisinfection is shown to infections. It is desirable to kill the entire microbial flora in the sulcus, as this could leave a patient open to other opportunistic pathogens. However, pathogens associated with periodontal disease are often difficult to eradicate due to the protected environment of the periodontal pocket. Photodynamic therapy, (PDT) is capable of effectively killing bacteria, including both wild and antibiotic resistant strains, viruses, yeasts, and parasites. These photosensitizing dyes by themselves are non-toxic to human hard and soft tissues and alternatively by themselves are not cytotoxic to pathogens. As chemical dyes however, they can be matched to selectively attach to only the desired pathogen species and thus avoid the potential for attachment to, and the subsequent destruction of, cells of the host organism when photoactivated. PDT has this unique advantage of dual selectivity, in that the photosensitzers can be targeted to very specific pathogenic organisms, and in addition, the illumination procedure can be localized to only the area of concern. This selectivity for microbes over host cells, the accurate delivery of the photosensitizers to the affected areas, and the dose adjustment abilities, help minimize side effects and give PDT an advantage over conventional therapies. The dyes can be controlled to selectively adhere to only pathogenic species of microbes leaving desirable bacterial species intact. It is not necessarily desirable to kill the entire microbial flora in the sulcus, as this could leave a patient open to other opportunistic infections.

When used in combination with normal routine scaling and root planning procedures, photodisinfection is shown to have significant improvements in post-operative healing success over the use of scaling and root planning alone. Photodisinfection procedures done in conjunction with scaling and root planning have been shown to statistically decrease the periodontal pocket depths of infected sites better than scaling and root planning alone. Photodisinfection has shown great promise as well, as an effective therapy for controlling bone loss in furcation areas in periodontitis.

Chemical antibacterial agents and mouthwashes are increasingly being used in prophylactic and therapeutic regimes for dental plaque-related diseases. As these agents are difficult to maintain at the therapeutic concentrations in the oral cavity and can be rendered ineffective by resistance development in the target organisms, there is a need for alternative therapies. Many pathogens are becoming resistant to antibiotics through their over-use in either systemic or topical applications. The continued reliance of antibiotics and anitiseptics agents creates the potential for mutagenic processes of these microbes or the selective resistance of microbial cells. PDT procedures are an effective alternative to these traditional treatment therapies as the method of action is from oxidative reactive processes and does not lead to bacterial-resistance. As microbial cell death is primarily a consequence of membrane photodamage, the risk for either the onset of mutagenic processes and or the selection of photoresistant cells has not been seen. This approach is therefore a useful alternative to antibiotic and antiseptics in eliminating periodontopathogenic bacteria while at the same time conserving the dwindling supply of antimicrobial agents that
are effective in the treatment of serious systemic infections.

**The specific Periowave™ Protocol for disinfection of infected periodontal pockets, as per the manufacturer is:**

1. Irrigation: After traditional scaling and debridement, Periowave™ photosensitizing solution is irrigated into an infected periodontal pocket. To thoroughly irrigate each treatment site with Periowave™ photosensitizer solution; place the irrigation cannula at the base of the treatment site pocket and slowly deliver the solution while gently moving the cannula back-and-forth in a mesiodistal direction. Continue to irrigate the pocket until a small quantity of solution can be seen flowing over the free gingival margin. Only one treatment area or site should be irrigated at a time to prevent gingival crevicular fluids from flushing out sensitizer solution out of the pockets of concern before the illumination step can be completed.

2. Illumination: The non-thermal diode laser light tip is inserted into the periodontal pocket and activated to illuminate the solution filled treatment area for a 60 second period. To achieve optimum results, the tip should be walked around the treatment area defect during illumination in both an apico-coronal and mesio-distal direction, without allowing the tip to rise above the gingival crest. Reactive oxygen species formation follows. These reactive oxygen species; 1) damage bacterial cell membranes facilitating the killing of these pathogenic bacteria, and 2) are capable of inactivating the virulence factors associated with these pathogens. Any pockets greater than 4 mm that present with bleeding on probing should be re-treated at 3 to 6 weeks to prevent the re-establishment of biofilms during the healing process. Very deep pockets, implant sites, and refractory pockets have a better healing response after a second application of the treatment protocol at the initial treatment appointment.

Periowave™ is ideally targeted for patients with bleeding on probing and all pockets of 4 - 9 mm length that bleed on probing. Periowave™ should only be used following a thorough scaling and root planing debridement and after any moderate to severe post-instrumentation bleeding has been controlled. Successive, (recall), treatments may benefit from light manual debridement prior to treatment. Each defect should be treated separately, and contralateral sides of each tooth checked, especially at interproximals, as these sites may benefit from additional photodisinfection as well. Long-term results may be significantly enhanced by a follow-up treatment 3-6 weeks after the first treatment. Patient outcomes should include a reduction or elimination of bleeding on probing, an improvement in gingival tissue tone and texture, and a reduction in pocket depth.

**Manufacturer(s):**
Ondine Biopharma Corporation  
#910 - 1100 Melville Street  
Vancouver, BC, V6E 4A6

Periowave™ is strictly a minimally invasive therapy for the destruction of pathogenic flora. The unit currently sells for under $5,000.00 Canadian which is the equivalent of about $4,000.00 U.S. and with all the attachments, kits, etc, is only about $7,000.00 Canadian - total. It has the potential to be a simplified tool for the entire dental team of a biological dental office, i.e. as it is marketed, for the hygienist to use in office, and without dentist supervision to effect a disinfection of the sulcular/diseased pocket areas. It has the ability to be one more tool in a limited family of effective treatment modalities, (i.e. versus drug or chemical therapies), for the average dentist to help his periodontally compromised patients achieve better oral health.

**Distributors:**
Henry Schein Canada, Patterson Dental Canada Inc., or Sinclair Dental Co. Ltd.

**Scientific Literature:**


Komerik N and MacRobert AJ., Photodynamic therapy as an alternative antimicrobial modality for oral infections. J Environ Pathol Toxicol Oncol. 2006; 25(1-2) : 487-504


Below are the titles from three sources of information provided by the manufacturer that would indicate their successes with periodontal pocket depth reductions while utilizing their system.

3. A Multi-Center, Randomized, Examiner-blinded Study of Photodisinfection in the Treatment of Chronic Periodontitis.

Legal Aspects of this Scientific Review: Periowave™ has been approved for sale and use by Health Canada since March of 2006. Ondine Biopharma Corp. is currently seeking FDA approval to distribute this product in the United States.

To date there are no known drug interactions with the use of the Periowave™ system. Theoretical there may be a concern for patients with severe Glucose-6-phosphate dehydrogenase deficiency but since the Periowave™ photosensitizer is not ingested during a normal treatment procedure, this outcome would be extremely unlikely and should therefore not be at risk to cause a reaction. Periowave™ is not contraindicated in pregnancy or lactating women.

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