HYBENX CLINICAL USES IN ORAL HEALTHCARE

HYBENX Oral Tissue Decontaminant (HOTD) was designed as a supplemental rinse and debriding agent for enhanced cleansing of dental plaque and other infectious matter from clinically important surfaces in the oral cavity. HOTD was not designed as a therapy for a specific disease. Its intended use is not tied to any particular clinical treatment outcome.

The importance of maximizing the cleanliness of oral cavity tissue surfaces to the achievement of optimum clinical results is a well-established principle in dentistry.

HOTD was intended to be regarded by the dental profession as a universal adjunctive cleaning tool. EPIEN Medical formulated the product so that individual dental practitioners could use it to enhance their performance of those professional techniques that are the most important for their specific practice. After practitioners have learned the mechanism of action of HOTD and acquired some basic experience in the application of HOTD to both healthy and diseased tissues in the oral cavity, they can then develop their own guidelines for use of the product to best enhance patient outcomes within their own individual practice setting.

Recent clinical research suggests that oral cavity microbes may have a pathological role beyond the mouth. Linkages between oral tissue infection and systemic conditions such as diabetes and coronary artery disease are becoming established. These issues mandate that dental practitioners do everything possible to control and minimize all possible risks that might arise from pathogens in the oral cavity.

As noted previously antiseptics and antibiotics have limited ability to suppress microbes that have become established within a biofilm and they have no effect on the biofilm matrix structure itself. The risk of developing antibiotic resistant microbes is also a challenge that needs to be addressed. Another major concern is that standard mechanical plaque removal techniques can contribute to infection control problems. Splatter from ultrasonic scaling equipment has been shown to create airborne droplets consisting of biofilm with viable pathogens that was carried throughout an entire clinic.

When HOTD is used in an adjunctive role it is uniquely able to overcome the limitations of established standard anti-plaque methods. HOTD is a liquid and it can be irrigated onto any surface in the oral cavity that can be reached by a liquid. It not only removes microbes, but it also attacks and denatures the entire plaque matrix which makes it more difficult for pathological microbes to become reestablished. Because the product acts by physically disrupting the microenvironment of plaque and necrotic tissues, resistance to the product cannot develop.

On the following two pages a table is presented that shows some basic examples and guidelines for the use of HOTD in the performance of specific professional procedures. The information in these tables is intended to suggest the range of possible applications of the product. It is not meant to be used as specific instructions in the application of HOTD in the manner of a package insert. As noted above, HOTD is an adjunctive therapy that is intended to be adaptable to the needs of individual practitioners as they look for ways to optimize their performance.

For all dental procedures, HOTD is applied with an irrigation syringe and a cannula for 10-60 seconds followed by rigorous rinsing with water and high-speed evacuation. HOTD enhances the efficacy of standard hygiene procedures by removing residual components of plaque biofilm that are left behind in pits, fissures, and crevices of tooth structures and gingival tissues after standard mechanical dental procedures. The following table includes suggestions for how HOTD can be implemented into routine dental procedures.

Procedure	Condition	HOTD is Used?	Benefits of HOTD	Concerns	Significance
Oral Prophylaxis	Routine cleanings, mild to moderate gingivitis	***Prior to cleaning:*** Apply HOTD one quadrant at a time to tooth and gingival tissues.	Removes superficial plaque biofilm, softens calculus, and removes active biofilm from splatter created during cleaning.	Up to 1 mL of HOTD per quadrant	Allows for faster and more efficient routine cleanings.
		After cleaning: Apply HOTD one quadrant at a time to tooth and gingival tissues.	Removes deep and residual plaque biofilm, seals dentinal tubules, and reduces tooth sensitivity.		
Scaling and Root Planing	Advanced gingivitis and Periodontal disease	***Prior to Treatment***: Apply HOTD to affected tooth and gingival tissues.	Removes superficial plaque biofilm— especially from inaccessible areas, softens calculus, enhances and hastens instrumentation techniques, removes active biofilm from splatter created during SRP.	Up to 1 mL of HOTD per quadrant	Allows the general practitioner a greater degree of confidence to adequately maintain patients with periodontal disease. Increased patient comfort
		After treatment: Apply HOTD to affected tooth and gingival tissues.	Reduces post-treatment bleeding and sensitivity, lessens inflammatory mediators, and enhances patient comfort.		
Dental Restoration	Dental Caries, Crown Preparations, Tooth Fractures	Apply HOTD after cavity preparation and prior to application of a primer. HOTD can be used instead of a hypochlorite rinse.	Removes dentinal smear layer, eliminates residual biofilm from the inside of the cavity preparation, debrides loose necrotic debris, reduces hemorrhaging at the treatment site, reduces the occurrence of bonding failures, and greatly reduces sensitivity.	Up to 0.5 mL of HOTD applied to the inside of the dental cane site.	Increased patient comfort and reduces the risk of restoration failure.

This Table is continued on the next page.

Examples of Clinical Procedures Using HOTD - Continued

Procedure	Condition	HOTD is Used?	Benefits of HOTD	Concerns	Significance
Vital Pulp Treatment	Reversible Pulpitis	Apply HOTD rinse, and cover the pulpal tissue with a glass ionomer followed by the restoration material.	Removes plaque biofilm contamination of the exposed pulp, removes dentinal smear layer,	Up to 1 mL of HOTD applied to the treatment area. HOTD is contra-indicated for use with calcium hydroxide paste.	Increased patient comfort and reduces the risk of restoration failure.
Dental Implant Maintenances		Apply HOTD to gingival tissue around the implant site.	Removes superficial plaque biofilm, reduces instrumentation damage to the implant, reduces inflammation, and shrinks the surrounding tissue to the implant by reducing edema. HOTD does not affect the implant.	Up to 1 mL of HOTD applied to oral mucosa surrounding the implant.	Increased patient comfort and lessens the risk of biofilm complications at the implant site.
Endodontic Treatment	Irreversible Pulpitis	After shaping the canal with citric acid or EDTA, apply HOTD to the root canal instead of hypochlorite. Complete the procedure as normal.	Removes plaque biofilm contamination from very inaccessible areas--including dentinal tubules, enhances restorations by drying the canal and improving the seal for the restoration material, reduces biofilm-related complications, the viscous nature of HOTD makes it less likely to leak through the root apex into bony tissues.	Up to 1 mL of HOTD applied to the inside of the root canal. HOTD is contra-indicated for use with indicated calcium hydroxide paste.	Makes a hypochlorite rinse unnecessary and allows the practitioner to work without fear of periapical extravasation of hypochlorite.
Extraction sites and soft tissue wounds	Various conditions	Using an application syringe, apply HOTD to a swab and treat the affected area with the HOTD-coated swab.	Reduces inflammation and edema of the wound site denaturing and coagulating the superficial oral tissue of the wound site. Lessens hemorrhaging at the wound site.		Increased patient comfort and lessens the risk of biofilm contamination of the wound area, and reduces complications.

The statements contained in the above chart reflect the opinions of dental practitioners who have evaluated HOTD. These statements have not been reviewed by regulatory agencies in Europe, Canada, or the United States. HOTD has been approved for marketing in the US by the FDA for ROOT CANAL CLEANSING as a Medical Device. Having been cleared for marketing as a Class I Medical Device in the EU, US and Canada, HOTD is now available to dental practitioners in those jurisdictions as an adjunctive focal irrigation solution intended for the removal of dental plaque biofilm and/or cleansing. HOTD is intended to be used as supplied at its full original concentration. Diluting with water and/or combining HOTD with another product will render it ineffective and potentially harmful.