

Frequently Asked Questions About *HYBENX*[®] Oral Tissue Decontaminant ("HOTD")

Always carefully read the Instructions for Use provided with *HOTD*. Also consider www.hybenx.it for further descriptions of clinical uses by your professional clinical colleagues.

As stated in the Instructions for Use, tissue surfaces should always be dried with cotton gauze and/or compressed air prior to the application of *HOTD*. In cases with excess bleeding, clinicians recommend that product be applied liberally to displace excess blood and fluid. This is because the product is less effective as it becomes diluted. Product should never be left in place for more than 30-60 seconds.

Unlike antibiotics and other cleaning agents, using "more" is not better. The beneficial action of *HOTD* is virtually instantaneous. Leaving it in place longer than recommended or overly aggressively scrubbing tissues with the product in place can lead to temporary hypersensitivity which may linger a few days. First time users are advised to practice a "less is more" mantra until they get used to the product action.

What is the difference between *HOTD* Liquid and *HOTD* Gel?

There is no difference in the active ingredients in these two versions of the product. The gel simply contains a small amount of silica to achieve a thicker viscosity. Some clinicians prefer to use the gel in clinical sites where the liquid might flow away from the treatment area. The gel is more likely to remain in place where it is used. Both products will demonstrate reduced viscosity as they warm to body temperature. Use of either form of the product is simply personal clinician preference based on the clinical procedure being performed.

How does *HOTD* work?

The action of *HOTD* is based upon the simple fast-acting principle of **Desiccation Shock Technology**[®] or **DST**[®]. **DST** is a simple physical process that desiccates (removes water) from the combination of infectious microbial material and dead cellular debris (biofilm) and macromolecules found in an infectious lesion. This effect denatures (destroys) the molecular structure of this infectious material and loosens attachment to the lesion surface. This process occurs within less than a minute after contact.

What is the clinical/regulatory status of the product?

HOTD has been cleared in the European Union and Canada as a Class I Medical Device for broad use in the oral cavity. In the USA it's sister product *HYBENX*[®] **Root Canal Cleanser** is a combination product that has been cleared by the US FDA as safe and effective for use as a medical device in root canal cleansing procedures.

Does **DST harm the mouth?**

No. Normal mucosal epithelium resists the instant desiccation process of **DST**. Incidental contact with the mucosal epithelium will cause a blanched (whitened) appearance of the superficial surface. This surface tissue is not permanently damaged and the effect will dissipate within a few days as natural rehydration occurs. In addition, the patient may detect an acidic sour taste or brief stinging under some circumstances. This is normal and transitory. *HOTD* has been used in over 8 million applications throughout the world. Less than 0.002% of those applications have resulted in complaints to EPIEN Medical, Inc. These complaints primarily referenced the undesirable taste, smell, or brief stinging that can be associated with the product or more rarely, a surface allergic response to sulfur.

What if *HOTD* contacts the skin outside the mouth?

DST acts in an extremely slow manner on intact non-mucosal skin and will generally have no effect upon accidental contact. It should be immediately removed with rinsing and it can damage clothing. Contact for excessive periods of time could yield a slight warming sensation.

Does *HOTD* harm clothing?

Yes, clothing can acquire pink staining and/or be damaged by incidental contact with *HOTD*.

What is the International clinical community saying about the use of *HOTD*?

According to their published presentations, clinicians offer the following guidelines from their experience with the product:

- In heavy plaque biofilm cases they first apply product and rinse before any debridement is attempted. They feel this helps loosen biofilm, reduce bleeding and patient discomfort, and makes mechanical debridement more effective. They sometimes briefly reapply product when finishing to finalize the cleansing and sealing of the debrided surfaces.
- They typically do not use antibiotics when using *HOTD*
- They use the product universally for any oral debridement procedure involving:
 - General cleaning,
 - Pre-restoration of excavated caries lesions
 - Cleaning of abscessed tissue sites
 - Pre- and post-mucosal surgery,
 - Peri-implant mucositis and implantitis
 - Aphthous ulcer amelioration
 - Cleaning fixed and removable prosthetics and orthodontic fixtures