



Instructions for Use: They're Meant to be Read!

Assumption of knowledge is a dangerous thing.

By Laura Thill

If you don't read the instructions that accompany your new iPhone, chances are you – or your teenage son or daughter – will figure it out. When it comes to dental equipment, however, assuming you know how to use a new product can lead to detrimental – even life threatening – consequences for your staff, your patients and your practice.

Particularly in the case of waterline treatment, noncompliance can lead to serious infection outbreaks, according to Leann Keefer, RDH, MSM, director, clinical services and education, Crosstex, a Cantel Medical Company. Nevertheless, dental professionals commonly refer to manufacturer instructions for

use (IFUs) only on a need-to-know basis, they point out.

“In order to get the most effective and efficient use of any product, compliance with IFUs is critical,” says Keefer. “With regard to documentation and training, everyone in the office needs to be on the same page with the technology, not

just the person who does the ordering. Procedures and policies of water management are an integral part of the office's infection control manual, and the IFUs are critical to use in protocol development.” Unfortunately, many dental offices set aside the IFUs, referring to them when they have a specific question. In fact, after adopting new technology, some dental teams assume they can transfer knowledge from previous clinical experiences, she adds. But, they do so “without necessarily being aware of the differences and

nuances in science, procedure or technique. Assumption of knowledge is a dangerous thing.”

Vigilance and caution

When adopting new waterline treatment technology, dental professionals are tasked with being extra cautious. For instance, it's not unheard of for a manufacturer of a validated water treatment system to omit providing a monitoring protocol in their IFU, notes Keefer. In this case, the dental practice should reach out to the manufac-

ture for a best-practice recommendation, she points out. In addition, the dental team must be aware of discrepancies in directions for use from one manufacturer to the next. “Dental offices need to be aware of the differences in instructions for use from both dental chair manufacturers and waterline treatment manufacturers and reach out to these manufacturers when IFUs provide conflicting information,” she says. “For example, a dental chair manufacturer may recommend the use of a

hypo-chlorite solution as an intermediate shock for bacterial reduction in the dental waterlines. However, use of this chlorine-based product may conflict with best practices for other automated dental waterline products that may be in use. “OSAP issued a white paper in September 2018 specific to waterlines that speaks to the importance of contacting dental chair manufacturers and waterline treatment manufacturers for specific guidance and instructions on methods to improve and maintain the quality of dental

water quality. The water management plan should include specific testing locations and frequencies, and actions to take (e.g., remediation, retesting at shorter intervals) based on test results. [Practitioners] should follow the manufacturer's instructions for cleaning and disinfecting the dental unit at recommended intervals. They should contact the manufacturer of the dental unit to obtain the most up-to-date instructions or direction for reprocessing of the dental unit.”

Risks and realities

It can't be said enough: When dental practitioners ignore DUWL treatment protocols, it places the staff, patients and, ultimately, the practice at risk. “Whether using a DUWL treatment like Crosstex DentaPure™ Cartridges or Liquid Ultra™ Solution, or a different DUWL treatment method, it is imperative that dental offices follow the instructions for use to ensure the chosen waterline treatment meets the product-approved claims for CFU/mL reduction to meet EPA standards of <500 CFU/mL,” says Keefer. “We frequently overlook the risk of the staff's constant exposure to contaminated bioaerosol. Clinicians work between 14-16 inches from a patient's mouth, and aerosol can carry over three feet. Studies have shown that occupational asthma is triggered due to endotoxins contained in aerosols.” (https://cdn.ymaws.com/www.osap.org/resource/resmgr/Docs/2_SADJFebruary_2009_REVIEWOc.pdf)

In a few widely publicized cases, it was the patients who suffered the most. In In 2015, contaminated

“In order to get the most effective and efficient use of any product, compliance with IFUs is critical. With regard to documentation and training, everyone in the office needs to be on the same page with the technology, not just the person who does the ordering.”

– **Leann Keefer, RDH, MSM, director, clinical services and education, Crosstex, a Cantel Medical Company**

procedure water,” says Keefer.

“Per FDA [guidelines], dental practitioners should consult with the dental unit manufacturer's instructions for the recommended maintenance schedule of the dental unit waterlines,” she continues. “Dental practitioners should adopt appropriate infection control procedures for dental unit water lines (DUWLs) based on the manufacturer's instruction for use. This should include infection control measures such as (but not limited to) monitoring

dental treatment water at a Georgia Pediatric dental clinic led to at least 23 children becoming infected after pulpotomies. Their ages ranged from 3 to 11, according to the Centers for Disease Control and Prevention. They had all been infected with *Mycobacterium abscessus*, a rapidly-growing bacterium known to contaminate waterlines in dental offices. (<https://www.ajc.com/news/local/georgia-didn-sanction-dental-chain-accused-infecting-children/5501Ebv2D27LyuerW1ywdI/>.)

In 2016, an Anaheim, California, pediatric dental clinic's water system became infected with *Mycobacterium*, causing over 70 children to be hospitalized following pulpotomies.

In early 2011, an 82-year-old woman in Italy contracted Legionnaires' disease, which was traced to equipment in a dental surgery she attended shortly before being hospitalized. Despite treatment and antibiotics administered at the hospital, she developed rapid and irreversible septic shock and died two days after being admitted. (https://www.eurekalert.org/pub_releases/2012-02/l-dow021412.php)

"At Crosstex, we provide a selection of literature that includes procedural guidance for following our DUWL IFUs after purchase, while addressing the evidence-based science behind why treatment is so important," says Ilene Russo, Crosstex waterline product manager. "We also provide live CE programs, as well as on-demand webinars covering the science, treatment choices and implementation (www.crosstexlearning.com)." In addition, Crosstex sales representatives refer dental offices to the CDC Summary



of Infection Prevention Practices in Dental Settings: Basic expectations for self-care (<https://www.cdc.gov/oralhealth/infectioncontrol/pdf/safe-care2.pdf>).

"Following IFUs is not a standalone issue for waterlines," says Keefer. "It's a standalone mindset for how we approach overall infection prevention and control in the

dental setting. This becomes both an ethical and a clinical choice when patient safety is in question. It should not take tragic headlines to ensure compliance. However, if reminding clinicians of the risks and realities associated with noncompliance shifts the paradigm, Crosstex will continue to keep these preventable incidents top-of-mind." ■