Illegal to Use Disinfectant Wipes or Other General Purpose Disinfectants to Disinfect Dental Instruments

Abstract
The use of disinfectant wipes for disinfecting dental instruments between patients is viewed all too commonly as an acceptable practice. To the contrary, the use of disinfectant wipes or any liquid disinfectant that is not FDA-cleared as a high-level disinfectant is in violation of Federal law. Unfortunately, due to the failure to thoroughly read label instructions, this practice continues in dentistry and can lead more importantly to patient and dental staff health risks from wiped instruments that still harbor sufficient microorganism populations which may lead to disease transmission.

Federal Oversight
Guidance documents by CDC, FDA, ADA, and other national standards organizations (e.g., ANSI/AAMI) have been written to provide direction to the dental community in achieving proper infection control. Providing documentation for their recommendations with scientific and statistical studies, these agencies provide direction to the dental community on the proper methods to sterilize instruments. These agencies state that only in limited circumstances is liquid disinfection an acceptable option to sterilization; that limitation being the incompatibility of the heat sterilization process (dry heat sterilization or steam sterilization processes) with instrument composition or function. Unfortunately, with seemingly no regulatory oversight, these guidance documents are viewed only as guidance and instrument disinfection with liquid germicides remains an all too common practice. It should be noted that these federal and national guidelines have been adopted as "Standard Operating Procedures (SOP's) by many state and local public health regulations, including dental accrediting bodies. Failure by the practitioner to adhere to these adopted SOP's can not only put a patient in jeopardy, but can also lead to an indefensible civil or regulatory liability.

The effectiveness of a liquid disinfectant is predicated on disinfectant concentration and time of microbial contact. It is with these factors that EPA and FDA require documentation that both conditions are achieved to meet required microbial killing efficacy thresholds as established for a particular application. In addition, both agencies have limitations on liquid disinfectant use to ensure that the disinfectant meets its required concentration and microbial contact thresholds during treatment. As such, the item to be disinfected must be non-porous so not to interfere with microbial contact and must be pre-cleaned to remove materials that interfere with microbial contact or disinfectant concentration. Instructions for use and restrictions to the use of a disinfectant are provided on the label, which has been approved by EPA or FDA with the issuance of an EPA Registration Number or FDA 510(k), respectively. Both FDA and EPA maintain updated lists of cleared/approved disinfectants.

In 2000 FDA was granted sole authority and jurisdiction to establish criteria for the regulation of liquid sterilants and high level disinfectants as medical devices for the sterilization/high level disinfection of medical and dental instruments (FR Vol. 65, No. 111, pg. 36324; 21 CFR Part 880.6885 and 880.6890).[1] FDA took the position that liquid sterilants and high level disinfectants were an accessory to reusable medical devices and as such, would be defined as medical devices, requiring a 510(k) to market those germicides under the specific conditions of use for specific purpose(s) as defined in 21 Code of Federal Regulations:

> "Sec. 880.6885 Liquid chemical sterilants/high level disinfectants.
> (a) Identification. A liquid chemical sterilant/high level disinfectant is a germicide that is intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use. Critical devices make contact with normally sterile tissue or with mucous membranes or body spaces during use. Semicritical devices make contact during use with mucous membranes or nonintact skin."

Also defined were general purpose disinfectants whose jurisdiction would remain under the EPA.

> "Sec. 880.6890 General purpose disinfectants.
> (a) Identification. A general purpose disinfectant is a germicide intended to process noncritical medical devices and equipment surfaces. Noncritical medical devices make only topical contact with intact skin. A general purpose disinfectant can be used to preclean or decontaminate critical or semicritical medical devices prior to terminal sterilization or high level disinfection."

Three points need to be emphasized:

(1) Liquid chemical sterilants/high-level disinfectants are regulated solely by FDA if they are to be used in the "terminal step in processing critical and semicritical medical devices prior to patient use." A 510(k) clearance is required. FDA provides a listing of current FDA-cleared sterilants and high-level disinfectants.[2]
(2) FDA defines a general purpose disinfectant as a germicide intended to process non-critical medical devices and equipment surfaces. A general purpose disinfectant may be used only to pre-clean or decontaminate a critical or semi-critical instrument, but not used as a final instrument processing step. General purpose disinfectants are regulated by EPA. General purpose disinfectants are not to be used to disinfect medical or dental instruments.
(3) General purpose disinfectants as regulated by EPA are subject to enforcement action under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and require all applicable label instructions on EPA-registered products to be followed (e.g., use-dilution). If the user selects exposure conditions (e.g., exposure time, disinfectant concentration) that differ from those on the label,

the user assumes liability for any injuries resulting from off-label use.[3] EPA maintains a listing of registered (approved) general purpose disinfectants.[4]

Importance of Following Disinfectant Label Instructions

Failure to follow label instructions prescribed by the EPA for general purpose disinfectants can easily lead to disease transmission by not effectively killing pathogenic organisms retained on an instrument from a previous patient or derived environmentally (e.g., C. diff.). In too many instances general disinfectants are misused in the mistaken belief that any disinfectant is good enough under any form of application.

As noted, general purpose disinfectants can be used on medical and dental instruments only to pre-clean or to decontaminate prior to terminal sterilization or high-level disinfection. General purpose disinfectants (e.g., CaviWipes®) are regulated by the EPA and as specifically delineated on the CaviWipes® label:

> "This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization/high-level disinfection."[5]

> "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."[5]

Summary

As specifically prescribed in Federal regulations, general purpose disinfectants such as Cavcide1® and CaviWipes® are not permitted under law to disinfect medical or dental instruments deemed critical or semi-critical in their patient application. These prescriptions are further stated on the label of all EPA-registered liquid disinfectants with the warning that to use the product otherwise violates Federal law enforceable under FIFRA, placing full responsibility on the user for misuse of the product. FDA has sole jurisdiction regarding the sterilization and high-level disinfection of medical and dental instruments and has explicitly stated that high-level disinfection can only be used when medical or dental instruments are heat-sensitive and cannot otherwise be sterilized.[6]

References

1. Title 21, Chapter 1 – Food and Drug Administration, Subchapter H, Part 880, Subpart G, Sec. 880.6885. 880.6890 – Liquid Chemical Sterilants/High Level Disinfectants; General Disinfectants.
2. FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices - March 2015 https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm437347.htm
3. Summary of the Federal Insecticide, Fungicide, and Rodenticide Act 7 U.S.C. §136 et seq. (1996) https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities
4. Selected EPA-registered Disinfectants**;** https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants
5. CaviWipes® Label; http://www.kellysolutions.com/erenewals/documentsubmit/KellyData%5CND%5Cpesticide%5CProduct%20Label%5C46781%5C46781-8%5C46781-8_CAVIWIPES_8_8_2012_1_27_31_PM.pdf
6. FDA, Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants. https://www.fda.gov/RegulatoryInformation/Guidances/ucm073773.htm

About the Author:

Nelson Slavik holds a B.A. in Biology (Kalamazoo College) and an M.S. in microbiology/biochemistry and a Ph.D. in Microbiology (University of Illinois at Urbana-Champaign, 1975). He served on the faculty of the Department of Health and Safety Studies at the University of Illinois at Urbana-Champaign and as the Biological Safety Director on campus for over ten years. Nelson served as chief environmental regulatory spokesperson and consultant for the American Society for Hospital Engineering of the American Hospital Association from 1984-1995. He has presented testimony (on behalf of the American Hospital Association) to the U.S. House of Representatives' Committee on Small Business, the U.S. Senate Subcommittee on Hazardous Wastes and Toxic Substances, and the U.S. Department of Transportation on environmental health and safety regulatory issues. He currently serves as co-founder, senior vice president, and technology director for Integrated Medical Technologies, Inc., which develops and markets loss control, patient safety, and surgical instrument sterilization technologies to the healthcare and dental industries. He currently holds two patents on new technologies to enhance surgical instrument sterilization.

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