EOSA The Ethylene Oxide Sterilization Association, Inc.
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POSITION STATEMENT

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Use of Ethylene Oxide to Sterilize Duodenoscopes

The Ethylene Oxide Sterilization Association, Inc. (EOSA) would like to communicate the best practices regarding health care facilities that are successfully using ethylene oxide (EO) to sterilize duodenoscopes for use in endoscopic retrograde cholangiopancreatography (ERCP) procedures. EOSA is a non-profit organization whose members include medical device manufacturers, sterilization consultants, laboratories, in-house and contract sterilizers, raw materials suppliers, and equipment manufacturers with a common interest in promoting the safe use of EO.

Benefits of EO Sterilization

Since its discovery as an effective sterilant, EO has played a critical role in antimicrobial sterilization to protect public health, and is essential to a functioning U.S. healthcare system. Decades later, it is now used to sterilize more than 20 billion medical devices each year in the U.S. alone. This represents more than 50 percent of all medical devices that are sterilized annually. The use of EO sterilization provides unparalleled health benefits to society by its use throughout the medical community. Numerous medical, hospital, and laboratory processes rely on EO to sterilize devices and equipment to protect millions of patients from the real risks of infectious diseases caused by bacteria, viruses, and fungi. EO sterilization is critical in the safe delivery of sterile devices and medical care.

The relatively low temperatures at which EO sterilization occurs provide the medical community significant advantages when sterilizing devices and products. Many critical healthcare products, such as duodenoscopes, are complex and sophisticated devices. For the majority of these healthcare products, EO sterilization is the most effective and efficient sterilization technology. The gentle yet thorough nature of EO allows for the sterilization of healthcare products and devices that would otherwise be destroyed and rendered unusable by radiation, moist heat, dry heat, other chemicals (gaseous or liquids), and other alternative sterilization methods.

High-Level Disinfection and Sterilization

The most common biocidal practice used for duodenoscopes and flexible endoscopes is high-level disinfection (HLD) using a liquid chemical disinfecting agent. Terminal sterilization with EO, however, is validated and even recommended for many types of endoscopes. Faster device reprocessing time is the primary reason HLD is a more common method than terminal sterilization with EO, even though there is a trade-off in the margin of safety. HLD and sterilization are two types of methods that reduce the overall levels of

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microbial contamination. Both methods are commonly employed by hospitals for reusable devices such as endoscopes.

Since HLD can be performed relatively quickly, it is often employed in hospitals for complex equipment or for equipment that might be used multiple times within a day. For HLD, the minimum requirement is to have a 6 log reduction of Mycobacterium species. The HLD process eliminates many or all pathogenic microorganisms except bacterial spores, while sterilization destroys or eliminates all forms of microbial life. EO is often used by hospitals or contract sterilizers for such sterilization. In fact, many endoscope manufacturers have suggested EO sterilization for endoscopes that are reused within hospitals.

Terminal sterilization of endoscopes with EO provides a greater margin of patient safety when compared to processing the same endoscopes via HLD or liquid chemical steriliants.[1,2,3] A traditional sterilization method, like EO sterilization, must be able to kill the equivalent of 12 logs (1,000,000,000,000) of the bacterial spores most resistant to the process and have a sterility assurance level (SAL) of 10^{-6}.[4,5] HLD, however, must only demonstrate that

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1 Centers for Disease Control and Prevention. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. William A. Rutala, Ph.D., M.P.H., David J. Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC).

2 U.S. Food and Drug Administration (FDA), *Liquid Chemical Sterilization*, available at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/ucm208018.htm.

3 FDA Center for Devices and Radiological Health. Guidance for Industry and FDA Reviewers, Content and Format of Premarket Notifications [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants. Jan. 3, 2000.

4 American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) ST67:2011. Sterilization of Health Care Products -- Requirements and Guidance for Selecting a Sterility Assurance Level (SAL) for Products Labeled "Sterile."

5 FDA Infection Control Devices Branch, Division of General and Restorative Devices. Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities. March, 1993.

it kills six logs (1,000,000) of the appropriate mycobacterium species most resistant to the chemical solution, and liquid chemical sterilization (LCS) must only demonstrate the ability to kill six logs (1,000,000) of the bacterial spores most resistant to the chemical solution.

A comparison of HLD versus sterilization supports the premise that sterilization of duodenoscopes can provide a greater margin of patient safety. EO sterilization should be considered over the benefit to reduced processing time. There is clinical evidence in peer reviewed, published literature for use of EO sterilization to increase the margin of patient safety in duodenoscope reprocessing. EO sterilization was used as part of the resolution of recent outbreaks of carbapenem-resistant Enterobacteriaceae (CRE) associated with the use of duodenoscopes.[6,7,8] Foliente, *et al.* was able to demonstrate that EO sterilization was able to eliminate all organisms from duodenoscopes in simulated use testing, while several methods of HLD were not.[9]

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6 Smith, Z.L., Oh, S.Y., Saeian, K., Edmiston, Jr., C.E., Khan, A.H., Massey, B.T., Dua, K.S. 2015. *Transmission of Carbapenemresistant Enterobacteriaceae During ERCP: Time to Revisit the Current Reprocessing Guidelines*. Gastrointestinal Endoscopy 81(4):1041-1045.

7 McCool, S. 2014. *High Level Disinfection Failure in Gastrointestinal Scopes with Elevator Channels -- Is It Time to Switch to Ethylene Oxide (ETO) Sterilization?* Abstract. ID Week. Oct. 7-11, 2014. San Diego, CA.

8 Epstein, L., Hunter, J., Arwady, M., Tsai, V., Stein, L., Gribogiannis, M., Frias, M., Guh, A., Laufer, A., Black, S., Pacilli, M., Moulton-Meissner, H., Rasheed, J.K., Avillan, J.J., Kitchel, B., Limbago, B.M., MacCannell, D., Lonsway, D., Noble-Wang, J., Conway, J., Conover, C., Vernon, M., Kallen, A.J. 2014. *NewDelhi Metallo-ß-Lactamase -- Producing Carbapenem-Resistant Escherichia Coli Associated with Exposure to Duodenoscopes*. JAMA. 312(14):1447-1455.

9 Foliente, R.L., Kovacs, B.J., Aprecio, R.M., Bains, H.J., Kettering, J.D., Chen, Y.K. 2001. *Efficacy of High-Level Disinfectants for Reprocessing GI Endoscope in Simulated-Use Testing*. Gastrointestinal Endoscopy. 53(4).

Work Place Safety

The EO sterilization industry is committed to safety, which is closely monitored. Workplace safety and practices continuously improve as EO sterilization equipment and processes advance with the introduction of advanced technology. In addition, sterilization processes are designed to ensure a safe work place. Many of these modern practices, designed for worker safety, have been recognized by FDA for use in the health care industry, including those used for endoscopes.[10]

AAMI and ANSI have developed consensus-based standards that are recognized by FDA.[11] By following these standards, hospitals and other healthcare facilities are equipped with current information to ensure the safe and effective use of EO sterilization in healthcare facilities and minimize any EO exposure to both workers and patients.

Patient Safety

The use of less effective processing methods can have significant adverse public health consequences. A change in sterilization technology could introduce the real risks of increased morbidity and mortality. For some healthcare products, proper microbial reduction levels may not be achieved other than through the use of EO sterilization. It is critical for endoscopes that are reused that they be processed in a safe and effective manner. The risk of patient-to-patient infectious transmissions with endoscopes is real and is well documented.

EO residual levels are tested and are qualified to meet all regulatory limits before they can be cleared to use, thus assuring patient safety.[12,13] A number of best practices for achieving this are currently available and practiced within the EO sterilization industry.

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10 Danielson, N.E. 1998. *Ethylene Oxide Use in Hospitals: A Manual for Health Care Personnel*. Third Edition, American Society of Healthcare Central Service Professionals of the American Hospital Association; Chicago, IL.

11 ANSI/AAMI ST41:2008(R)2012. *Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness.*

12 ANSI/AAMI ST24:1999/(R)2013. *Automatic, General-Purpose Ethylene Oxide Sterilizers and Ethylene Oxide Sterilant Sources Intended for Use in Health Care Facilities.*

Best Practices and Guidelines for Reprocessing Duodenoscopes and Endoscopes at User Facilities to Minimize the Transmission of Infection

Reusable endoscopes are approved by FDA. It is critical for facilities that are processing these devices to work with the product manufacturer(s) and sterilization service provider(s) to ensure that all current standards and procedures are being followed. This applies to both preparation for sterilization, and the sterilization procedure itself. Furthermore, several manufacturers have and can provide processing instructions for this use.

If you have any questions, or would like to request additional information, please do not hesitate to contact EOSA at 410-255-2773 or jvandevort@bc-cm.com.

[13] ANSI/AAMI/ISO 10993-7:2008. *Biological Evaluation of Medical Devices -- Part 7: Ethylene Oxide Sterilization Residuals*.