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Chlorine Dioxide Debuts in Updated Standards for Healthcare Sterilants and High-Level Disinfectants

Unique foam and wipe system offers fast, efficient, and economical high-level disinfection for ultrasound transducers and probes

FAIRFIELD, NJ -- An updated standard compiled by the Association for the Advancement of Medical Instrumentation (AAMI) and adopted by the American National Standards Institute (ANSI) has acknowledged chlorine dioxide foam as a novel modality for high-level disinfection of medical devices.

The updated standard for the US market echoes a 2024 update of guidelines from the World Federation for Ultrasound in Medicine and Biology, which included chlorine dioxide in its instructions for the cleaning and disinfection of endocavitary ultrasound probes.

The newly revised AAMI standard, *Chemical Sterilization and High-Level Disinfection in Health Care Facilities* (ANSI/AAMI ST58:2024), replaces previous versions and provides guidance on FDA-cleared liquid chemical sterilants, high-level disinfectants, and gaseous chemical sterilizers. It is intended as a guide for professionals in hospitals, labs, and other healthcare facilities.

Among the changes incorporated in the revised standard is the recognition of a residue removal step as defined in the instructions for use of chlorine dioxide foam. Historically, rinsing with water was the only option recommended under the standard. Now, the use of other residue removal procedures defined by the manufacturer has been recognized and included as an alternative solution.

According to AAMI, adopting and implementing ST58 will be critical for preventing healthcare-associated infections. Healthcare professionals can use the updated document to protect patients and demonstrate conformance with best practices.

Chlorine Dioxide in US Healthcare Settings

Parker Laboratories manufactures and distributes chlorine dioxide foam products for US healthcare markets under an exclusive commercial partnership with UK-based Tristel plc (AIM: TSTL). The company's Tristel ULT is a formulation that uses a proprietary foam and wipes to perform high-level disinfection and residue removal for ultrasound transducers.

Tristel ULT received FDA De Novo clearance in June 2023, creating a new category of Class II devices with the generic name 'foam or gel chemical sterilant/high-level disinfectant' intended for use as the final step in high-level disinfection (HLD) of medical devices prior to patient use.

Although chlorine dioxide is relatively new to US healthcare markets, the compound has a decades-long history of use in overseas markets. As a high-level disinfectant, Tristel ULT has been tested for efficacy against bacteria, fungi, mycobacteria, and viruses. In studies involving clinically relevant microbes, Tristel ULT was found to be capable of eradicating a wide range of pathogens, including *Candida albicans*, hepatitis viruses A, B, and C; human immunodeficiency virus (HIV); human papillomavirus (HPV) types 16 and 18; and *Mycobacterium terrae* (a surrogate for *M. tuberculosis*). In addition, Tristel ULT passed the AOAC International sporicidal activity test.

“Asepsis is paramount in infection prevention, especially when we know that up to 60% of central line-associated bloodstream infections are linked to skin flora,” says infection prevention expert Constance J. Cutler, MS, BS, BSN, CIC, FSHEA, FAPIC. “Prioritizing patient safety means implementing disinfection strategies that are both effective and efficient. The proven performance of chlorine dioxide in reducing microbial contamination presents a strong business case for its adoption, offering a reliable solution that aligns with both clinical and operational goals.”

Key Advantages

Tristel ULT is delivered in a novel dosing bottle with two separate compartments. One compartment contains the Tristel Part A solution (sodium chlorite) and the other contains the Tristel Part B solution (citric acid). When the pump is pressed, the two solutions mix, generating a precise and consistent dose of chlorine dioxide foam.

Compatible with more than 1000 transducer models, Tristel ULT offers advantages over competing HLD products that can make it especially suited for use in a wide variety of clinical settings:

- **Rapid Action.** Tristel ULT achieves high-level disinfection quickly, reducing device turnaround time in high-volume, fast-paced healthcare settings.
- **Easy to Use.** The application process includes a manufacturer-defined residue removal step, now formally recognized by AAMI, improving workflow efficiency.
- **Cost-Effective.** Tristel ULT’s ease of use eliminates the need for expensive automated systems, making it accessible for facilities of all sizes.
- **Portable and Practical.** Requiring no electricity or water, Tristel ULT is both compact and portable—ideal for point-of-care device processing in all healthcare settings, and particularly for remote or resource-limited locations.

“Adopting Tristel ULT has enabled us to better allocate the clinic staff’s time to patient care,” says Matthew Allaway, MD, a urologist with Urology Associates (Cumberland, MD), and founder and CEO of the medical device company, Perineologic. “As a result, we have increased the number of life-saving procedures we can perform during a typical workday. These efficiencies have improved the overall efficiency of our practice and reduced unnecessary costs and waste.”

As healthcare facilities continue to seek faster and more-effective solutions for high-level disinfection, the adoption of chlorine dioxide foam has gained momentum worldwide.

“Having seen the positive impacts of point-of-care high-level disinfection using chlorine dioxide foam at clinical sites using the ExactVu Micro-Ultrasound System in Europe, Exact Imaging applauds AAMI’s guideline update,” says Randy AuCoin, president and CEO of Exact Imaging (Markham, ON, Candada). “The Tristel ULT product is validated for use with our EV29L transducer and has already helped many practices safely increase their throughput to provide better care to more patients with micro-ultrasound.”

Other vendors have developed a method for generating chlorine dioxide in a gaseous formulation that is gentle on materials and is an EPA-registered sterilant. Interest in this formulation has grown recently because of its potential as a safer method for sterilizing medical products, replacing both ethylene oxide and gamma irradiation. Information about the use of chlorine dioxide as a sterilant is now included in an AAMI technical information report, *Compatibility of Materials Subject to Sterilization* (AAMI TIR17:2024), which is intended to help manufacturers qualify materials for use in products requiring sterilization.

About Parker Laboratories

Parker Laboratories is a leading global medical product company that develops, manufactures, and sells ultrasound and electromedical contact media and accessories, as well as leading lines of instrument cleaners and disinfectants. A worldwide leader in ultrasound medical products for over 65 years, Parker has consistently been at the forefront of technological advances in the industry. Its flagship product, Aquasonic 100 ultrasound transmission gel, is the world standard for medical ultrasound. For more information, visit www.parkerlabs.com.

Additional Resources

- Tristel ULT Product Backgrounder
- Tristel ULT Features and Benefits
- Tristel ULT Device Compatibility Summary

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