



PARKER LABORATORIES, INC.

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FDA Grants De Novo Clearance to Tristel ULT™ as a High-Level Disinfectant for Ultrasound Applications

Unique chlorine dioxide foam offers fast, efficient, and economical disinfection for ultrasound transducers and probes

FAIRFIELD, NJ—Parker Laboratories Inc., a worldwide leader in ultrasound supplies and accessories, has announced the US Food and Drug Administration (FDA) has [granted clearance](#) for a unique disinfecting foam, called Tristel ULT, as a high-level disinfectant for ultrasound probes used within body cavities and for skin-surface transducers.

Tristel ULT is manufactured and distributed for US markets by [Parker Laboratories](#) under an exclusive commercial partnership with UK-based Tristel plc (AIM: TSTL). Tristel ULT is a high-level disinfectant using a proprietary foam containing chlorine dioxide, which is widely used to disinfect drinking water and which a [recent major review](#) confirms as “a safe and effective disinfectant.” It is the only high-level disinfectant foam that can be safely used on ultrasound probes, and it has been shown to be effective against pathogens ranging from SARS-CoV-2 to *Mycobacterium tuberculosis*.

“More than 215 million ultrasound scans are performed in the United States each year, with approximately 20% of them requiring high-level disinfection,” says Neal Buchalter, president of Parker Laboratories. “Tristel ULT is the first product of its kind in the US, a high-level disinfectant foam for reprocessing ultrasound probes. As the exclusive manufacturer of Tristel ULT and Tristel DUO in the US, Parker Laboratories now offers a complete line of disinfecting solutions for ultrasound departments. These new products are just a few of the innovative and cost-effective solutions we are committed to bring to market to increase patient safety and improve workflow in the healthcare setting.”

About Tristel ULT

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. The process does not require electricity

or water, making it ideal for remote locations. The product is also less expensive, quicker, and easier to use than other methods of high-level disinfection currently on the market.

Because of these unique features, Tristel ULT represents an important advance, clinicians say.

"The availability of a rapid and inexpensive high-level disinfectant for ultrasound transducers will be an excellent tool for a fast-paced, high-volume ultrasound department, where turnover of equipment and prep for subsequent patients is paramount for efficiency," says sonography educator Candace Goldstein, BS, RDMS. "Such rapid disinfection is a real help for sonographers because it ensures that each patient has the benefit of high-level disinfection prior to their examination."

FDA's action came in response to Tristel's request for a De Novo classification of Tristel ULT as a high-level disinfectant for ultrasound probes. In granting Tristel's request, FDA created a new category of Class II devices with the generic name 'foam or gel chemical sterilant/high-level disinfectant.' FDA describes products in the new category as:

A foam or gel chemical sterilant/high-level disinfectant is a germicide in the form of a foam or gel that is intended for use as the terminal step in high-level disinfection of medical devices prior to patient use.

Previously, Parker and Tristel had received approval from the US Environmental Protection Agency for a chlorine dioxide formulation, [Tristel™ DUO](#), for the cleaning and intermediate-level disinfection of general medical surfaces and equipment.

Tristel ULT will make its US debut at the annual meeting of the Association for Professionals in Infection Control and Epidemiology (APIC), June 26–28, in Orlando. Both Parker Laboratories (booth 1540) and Tristel (booth 1541) will be exhibiting, and demonstrations of Tristel ULT will be held throughout exhibit hours.

Full US product launch and market availability of Tristel ULT is scheduled for October 2023. To receive product updates, register at www.parkerlabs.com/products/tristel-ult or contact Parker Laboratories at (973) 276-9500 or via e-mail at customerservice@parkerlabs.com.

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](#)

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