LABORATORIES, INC.
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Tristel ULT™
Product Backgrounder

A New Category of Disinfectant

On June 2, 2023, FDA granted a request from UK-based Tristel plc for De Novo classification of the company's patented chlorine dioxide disinfectant, Tristel ULT, for use with ultrasound transducers. 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.

Tristel's chlorine dioxide disinfectants are used in more than 40 countries and for millions of disinfection procedures every year. Tristel estimates more than 215 million ultrasound scans are performed in the United States each year. Approximately 20% of such scans require high-level disinfection of the transducer, while the remainder require low- or intermediate-level disinfection.

Tristel ULT is manufactured and distributed for US markets by Parker Laboratories under an exclusive commercial partnership with Tristel plc (AIM: TSTL). Parker Laboratories has been a worldwide leader in ultrasound supplies and accessories for more than 65 years. With FDA's clearance of Tristel ULT, Parker Laboratories now offers four products to meet the cleaning and disinfection needs of all ultrasound applications:

- **Protex®** Disinfecting Spray for low-level disinfection
- **Protex® ULTRA** Disinfectant Wipes for low-level disinfection
- **Tristel™ DUO** foam for intermediate-level disinfection effective against mycobacteria and bloodborne pathogens
- **Tristel ULT™** foam and applicator wipes for high-level disinfection

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High-Level Disinfection Capabilities

Tristel ULT is a proprietary chlorine dioxide foam intended for the high-level disinfection of cleaned, reusable, non-lumened ultrasound transducers, including endocavitary transvaginal and transrectal probes and skin-surface transducers that may contact non-intact skin during use.

Tristel ULT foam must be applied to the surface of an ultrasound transducer using Tristel ULT wipes. The dry wipes are made of a soft, durable, and low-linting fabric that will not leave a buildup of lint on medical devices. Each wipe is low-absorbing, to ensure the maximum amount of foam is distributed onto the medical device. The wipes are also used to remove any foam residue remaining after disinfection is complete. With a disinfection contact time of 2 minutes, Tristel ULT is the fastest high-level disinfectant with FDA market authorization.

Chlorine dioxide is an oxidizing biocide that deactivates microorganisms by attacking and penetrating their cell walls, disrupting the transport of nutrients across the cell wall by inhibiting protein synthesis. As this deactivating action occurs regardless of the metabolic state of the organism, oxidizing biocides are effective even against dormant organisms and spores.

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 effective against all the following organisms:

- *Candida albicans*
- Carbapenem-resistant *Klebsiella pneumoniae* (CRKP)
- *Chlamydia trachomatis*
- Extended-spectrum beta-lactamase (ESBL) producing *Escherichia coli*
- Human immunodeficiency virus (HIV).
- Human papillomavirus (HPV) type 16 and type 18.
- *Mycobacterium terrae*
- *Neisseria gonorrhoeae*
- *Streptococcus agalactiae*

In addition, Tristel ULT passed the AOAC International sporicidal activity test.

Clinical in-use studies in US hospitals have confirmed the performance of Tristel ULT in clinical settings, with no organisms recovered from patient-contaminated ultrasound probes disinfected with Tristel ULT.

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User Safety and Device Compatibility

The biocompatibility of Tristel ULT has been assessed for both 100% concentrated strength and through the evaluation of residues remaining on devices after high-level disinfection. Full-strength testing found Tristel ULT to be non-mutagenic, non-clastogenic in maturing erythrocytes, and non-toxic when taken orally. Testing of Tristel ULT residues were found not to be irritating to dermal, vaginal, or rectal tissues. Tristel ULT is classified as a slight irritant to the skin and an eye irritant when in direct contact.

More than a dozen ultrasound manufacturers have tested the Tristel chemistry for compatibility and have listed the compound as approved for use with specific models of their transducers. Manufacturers that have listed Tristel ULT as compatible with their products include:

- Alpinion Medical
- Bard Access Systems
- BK Medical
- Butterfly Network
- Canon Medical Systems (Toshiba)
- Carestream
- Esaote
- Fujifilm Healthcare (Hitachi)
- GE Healthcare
- Healcerion
- Mindray
- Philips
- Quantel Medical
- Samsung Healthcare
- Siemens Healthineers
- SonoScape
- SuperSonic Imagine
- Verathon

Tristel ULT is not hazardous during shipment and can be transported by land, sea, and air without restrictions.

Contact Parker Laboratories for additional information.