Tristel ULT™

HIGH LEVEL DISINFECTANT FOAM FOR ULTRASOUND PROBES

PARKER LABORATORIES, INC.

FDA APPROVED - 2 MINUTE CONTACT TIME - TRUSTED WORLDWIDE

TRISTEL ULT


Tristel
ULT™
WIPES
DRY WIPES FOR USE
WITH TRISTEL ULT FOAM
2 MINUTE CONTACT TIME
Use Tristel ULT Wipes within 6 months from opening. Do not exceed expiry date.
Date opened:
Use by date:
PARKER
Distribution partner in the USA
Tristel
ULT™
FOAM
HIGH LEVEL
DISINFECTANT FOAM
FOR ULTRASOUND
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PARKER
Distribution partner in the USA

INTRODUCING TRISTEL ULT

Tristel ULT is a high level disinfectant foam for reprocessing ultrasound probes.

Tristel ULT can be used to high level disinfect endocavity transvaginal and transrectal probes, and skin surface transducers that may contact non-intact skin during use.

Used by professionals in 35 countries since 2008, Tristel ULT is now FDA-approved for sale in the United States.

Tristel ULT is a prescription device under 21 CFR Part 801.109, classified as a Class II device under the generic name foam or gel chemical sterilant/high level disinfectant.

READY-TO-USE DESIGN

Tristel ULT is a ready-to-use foam with a wipe, it does not require installation, plumbing, water or electricity.

FAST CONTACT TIME

At 2 minutes, Tristel ULT is the fastest FDA-cleared high level disinfectant.

ACCESSIBILITY

Tristel ULT is compact, mobile and can be used at a site closest to the point of care.

COMPATIBILITY WITH ULTRASOUND PROBES

Tristel ULT is compatible with 965 probes and transducers from leading manufacturers.

PROVEN EFFICACY

Tristel ULT is a high level disinfectant and is effective against HPV type 16 and type 18.

IMPROVED CLINICAL OUTCOMES

Tristel ULT use increases probe availability and enables healthcare staff to attend to more patients.

TRISTEL ULT

UNIQUE DESIGN

Tristel ULT is a device which incorporates intuitive design features, operating as ready-to-use, thus securing successful user handling and dosing of the high level disinfectant at or above the specified Minimum Recommended Concentration (MRC).
A measured dose delivery is ensured with each application.

MRC CHECK

MRC of Tristel ULT may be verified using Tristel Test Strips, semi-quantitative chemical indicators.

Tristel Test Strips detect the MRC and above giving a color indication of a “PASS” and if the concentration is below the MRC a color indication of a “FAIL”.

Minimum Recommended Concentration (MRC): ~90% v/v (~280ppm) at point of use.

EASY TO USE

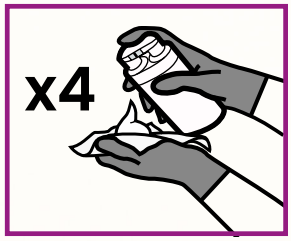
Tristel ULT Foam is applied on the surface of an ultrasound probe using Tristel ULT Wipes. Tristel ULT Wipes are dry, non-woven, low-linting wipes.

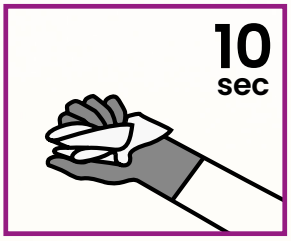
A user lays the Tristel ULT Wipe in one hand and applies 4 doses of the Tristel ULT Foam before closing their hand around the wipe and waiting for 10 seconds.

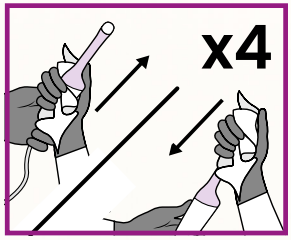
The wipe is used to spread the foam in a massaging motion from one end of the device to the other 4 times.

After the device is wiped, it is left undisturbed for 2 minutes.

A Tristel ULT Wipe is used to remove residue of the foam after high level disinfection. Refer to the Tristel ULT User Guide for full user instructions.







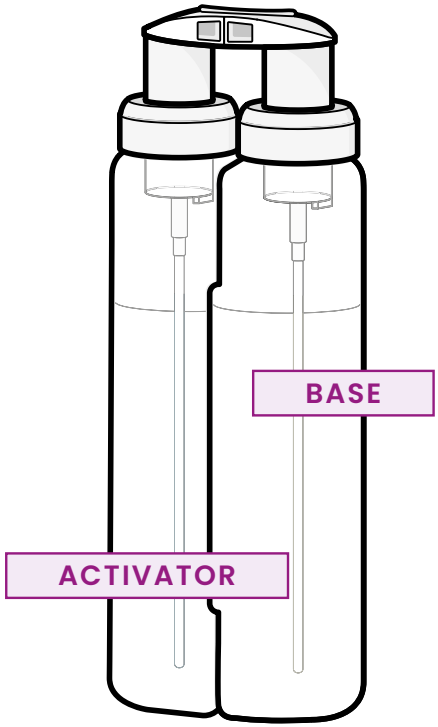
POWERED BY TRISTEL ClO_2

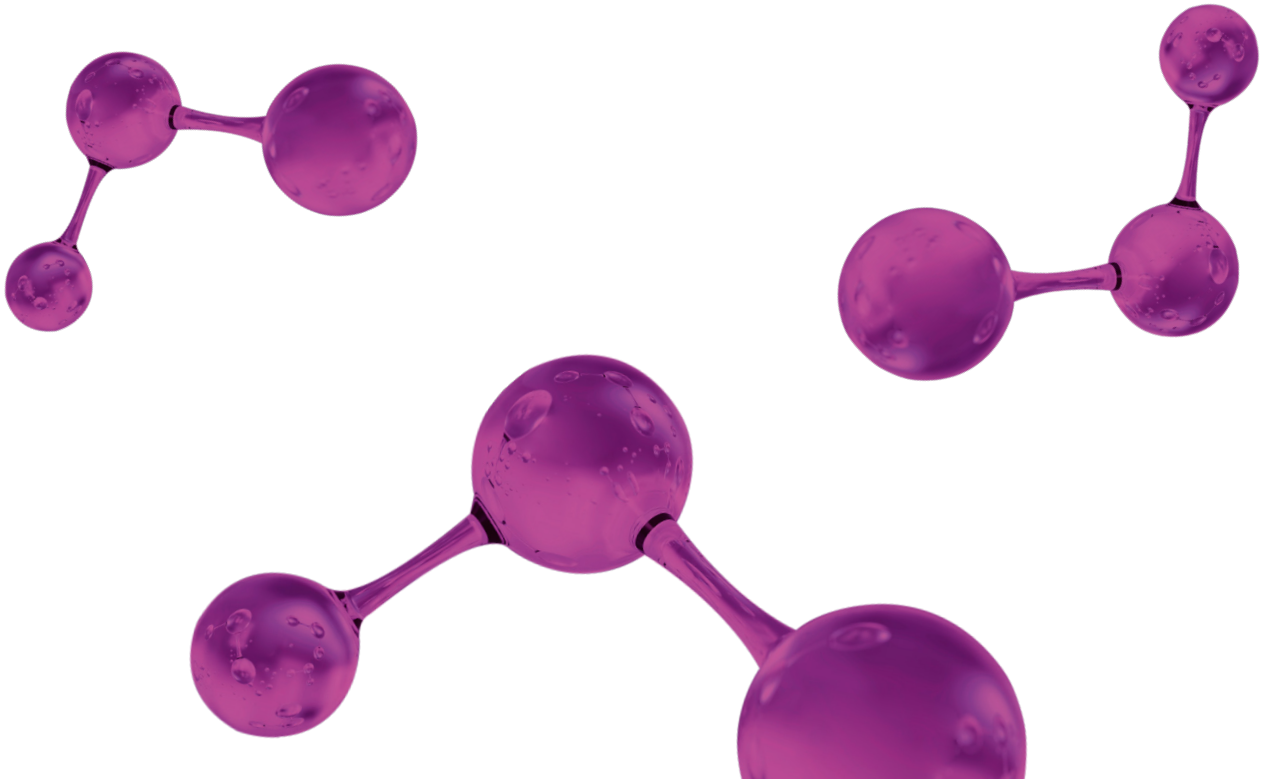
Tristel ULT is based on Tristel's proprietary chlorine dioxide (ClO_2) chemistry.

Tristel ULT generates chlorine dioxide foam from two "precursor" solutions (Base Solution and Activator Solution), which are packaged separately within two individual containers and secured together within a single dispenser apparatus known as the "pump."

Chlorine dioxide is an oxidizing biocide. It deactivates microorganisms by attacking and penetrating their cell wall, disrupting the transport of nutrients across the cell wall by inhibiting protein synthesis.

As this action occurs regardless of the metabolic state of the organism, oxidizing biocides are effective against dormant organisms and spores.





MICROBIAL EFFICACY

Tristel ULT is a high level disinfectant with a contact time of 2 minutes. As a high level disinfectant Tristel ULT was tested for efficacy against mycobacteria, viruses, fungi and bacteria. Tristel ULT passed the AOAC Sporicidal Activity Test.

Specific testing was carried out for clinically relevant microbes.

- Tristel ULT was tested for efficacy against Human papillomavirus type 16 (HPV16) and type 18 (HPV18) in a study conducted by Dr. Craig Meyers at the Pennsylvania State College of Medicine, USA. The study concludes that Tristel ULT is successful at inactivating HPV16 and HPV18.[1]

- Tristel ULT is efficacious against:
    - *Chlamydia trachomatis*
    - *Neisseria gonorrhoeae*
    - Carbapenem resistant *Klebsiella pneumoniae* (CRKP)
    - Extended-Spectrum beta-lactamase (ESBL) producing *Escherichia coli*
    - *Streptococcus agalactiae*
    - *Candida albicans*
    - Human Immunodeficiency Virus (HIV) Type 1
    - Hepatitis B Virus Surrogate Duck Hepatitis B Virus

Simulated device studies with *Mycobacterium terrae* validated efficacy on ultrasound probes. Clinical in-use studies in US hospitals confirmed the performance of Tristel ULT in clinical settings with no organisms recovered from patient contaminated ultrasound probes which were high level disinfected with Tristel ULT.

[1] Meyers C, Milici J, Robison R. The ability of two chlorine dioxide chemistries to inactivate human papillomavirus-contaminated endocavitary ultrasound probes and nasendoscopes. J Med Virol. 2020 Aug;92(8):1298-1302. doi: 10.1002/jmv.25666. Epub 2020 Feb 4. PMID: 31919857; PMCID: PMC7497195.

TRISTEL ULT

COMPATIBILITY

Tristel ULT has been tested and confirmed compatible with representative medical devices of leading manufacturers, including:

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

Scan the QR code to see the list of ultrasound probes compatible with Tristel ULT.

SAFETY

Tristel ULT biocompatibility was assessed on the 100% concentrated strength and through evaluation of residues left on devices after high level disinfection.

Tristel ULT is non-mutagenic, non-clastogenic in maturing erythrocytes, and not toxic when orally administered. It is classified as a slight irritant to the skin and an eye irritant in direct contact.

Any potential residues remaining have not been found irritating to dermal, vaginal and rectal tissues.

TRISTEL ULT

TRACEABILITY

3T is a fully featured, cloud-based device reprocessing compliance platform.

3T combines an intuitive mobile app for use at the point of care with an interactive web portal. It provides users with a valuable tool for record and traceability of device reprocessing.

3T guides users through the device reprocessing steps, tracking each event and making the record available to view in real time.

Aggregated data from device reprocessing events are securely stored and can be found across interactive dashboards, allowing administrators to view and share customised reports.

For manual traceability a log sheet is available to download.

Scan the QR code to find out more.

HOW TO ORDER

CONTACT PARKER LABORATORIES

EMAIL: customerservice@parkerlabs.com - **CALL:** 973.276.9500

TRISTEL ULT

PRODUCT CODE	DESCRIPTION	CASE CONTENTS
45-25	Tristel ULT: A dual compartment bottle and a tub of wipes. User Guide. Each set delivers 75 HLD cycles.	2

TRISTEL TEST STRIPS

PRODUCT CODE	DESCRIPTION	CASE CONTENTS
45-13	Tristel Test Strips starter pack: A vial/bottle of 50 test strips. Stopwatch. Polyethylene container. 10ml measure syringe. User Guide.	1
45-10	Tristel Test Strips: A vial/bottle of 50 test strips. User Guide.	1

TRANSPORT

Tristel ULT is not dangerous for shipment and can be transported by air, road and sea without restrictions.

Tristel™
WE HAVE CHEMISTRY

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