USER GUIDE

Tristel ULT™

HIGH LEVEL DISINFECTANT FOAM FOR ULTRASOUND PROBES

2 MINUTE CONTACT TIME

PARKER Distribution partner in the USA

INTENDED USE

Tristel ULT is a high level disinfectant foam intended to disinfect cleaned, reusable, non-lumened ultrasound probes. Tristel ULT is intended to be used by qualified healthcare personnel.

Tristel ULT does not sterilize.

INDICATIONS FOR USE

Tristel ULT is a high level disinfectant foam for reprocessing ultrasound probes. It can be used to high level disinfect endocavity transvaginal and transrectal probes, and skin surface transducers that may contact non-intact skin during use.

Tristel ULT is a high level disinfectant when used in accordance with the Directions for Use, including a disinfection contact time of 2 minutes, at room temperature and a concentration at or above Minimum Recommended Concentration (MRC).

Tristel ULT Foam must be applied on the surface of an ultrasound probe using **Tristel ULT Wipes**.

Tristel ULT Wipes are intended for application of Tristel ULT Foam on the surface of ultrasound probes and to remove residue of the foam after high level disinfection.

Each dose of Tristel ULT Foam and each Tristel ULT Wipe are **single use**.

The semi-critical ultrasound probes processed by Tristel ULT must first be cleaned according to a validated cleaning protocol or standard and following the device manufacturers' instructions.

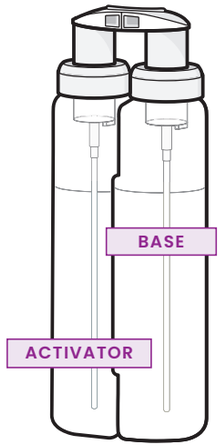
Tristel ULT Foam bottle is designed in a way that ensures measured dose delivery with each application generating active ingredient above the MRC.

Minimum Recommended Concentration (MRC): ~90% v/v (~280ppm) at point of use. MRC of Tristel ULT may be verified using Tristel Test Strips.

ACTIVE INGREDIENT

Tristel ULT Foam is made of two solutions, Tristel ULT Activator solution and Tristel ULT Base solution, which are mixed when dispensed to generate active ingredient chlorine dioxide. In-use concentration of chlorine dioxide (ClO_2) is 0.032% (320ppm).

Tristel ULT Foam Activator and Base solutions are contained in a dual compartment bottle with a dispenser pump and are ready to use.



Tristel ULT Activator	
Key Ingredient:	
Sodium chlorite	0.5%
Other ingredients	99.5%
Total	100.0%

Tristel ULT Base	
Key Ingredient:	
Citric acid	5.26%
Other ingredients	94.74%
Total	100.00%

Tristel ULT Foam is supplied with Tristel ULT Wipes. Tristel ULT Wipes are dry wipes made of a non-woven and low-linting material. Tristel ULT Wipes are intended to apply Tristel ULT Foam on the surface of ultrasound probes and to remove residue of the foam after high level disinfection.

CONTRAINDICATIONS

1. Do not use if the Tristel ULT Foam bottle or Tristel ULT Wipes tub are damaged, for longer than the prescribed contact time, or on non-compatible devices.
2. Tristel ULT Foam efficacy may be compromised if it is used with wipes other than Tristel ULT Wipes, and if user instructions are not followed in full.
3. Not intended for single use devices.
4. Tristel ULT should not be used to sterilize medical devices.

PRECAUTIONS

Follow OSHA Blood borne Pathogens Universal Precautions when handling and cleaning soiled devices.

1. Wear gloves and safety glasses when reprocessing devices.
2. Tristel ULT Wipes are dry and have no disinfectant properties without Tristel ULT Foam.
3. Use Tristel ULT in a well-ventilated area.
4. Clean devices thoroughly prior to disinfection. Residual contamination with soil or lubricants will decrease the effectiveness of the disinfectant. Follow device manufacturer's instructions.
5. Remove chemical residues following high level disinfection to avoid exposure to chemical residues.
6. Do not use Tristel ULT with the following materials: anodized aluminum, polyurethane elastomer 35A and polyurethane elastomer 90A. Testing has shown that Tristel ULT is not compatible with these materials.
7. The user MUST adhere to the Directions for Use, as modification to the Directions for Use may affect the performance and safety of the disinfectant.
8. Do not perform more than 20 disinfection procedures per day (8 hours). The limitation to 20 procedures per day for an operator is based on the 8-hour OSHA permissible occupational exposure limit for chlorine dioxide.
9. Do not use Tristel ULT Foam beyond 6 months after opening.
10. Do not use Tristel ULT Wipes beyond 6 months after opening.

TOXICOLOGICAL INFORMATION

Tristel ULT has been evaluated for biocompatibility.

Tristel ULT is non-mutagenic, non-clastogenic in maturing erythrocytes, and non-oral toxic. It is classified as a slight irritant to the skin and an eye irritant in direct contact.

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

Tristel ULT was evaluated for inhalation exposure during use. In a study simulating 20 disinfection procedures, the average 8-hour TWA readings did not exceed the U.S. OSHA permissible exposure limit of 0.1ppm for chlorine dioxide, and the results of the average 15-minute STEL readings did not exceed the California Division of Occupational Safety and Health PEL of 0.3ppm.

See WARNINGS for any possible adverse reactions.

WARNINGS

Based on biocompatibility testing, Tristel ULT Foam is irritating to the eye and is classified as a slight irritant to the skin.

Eye Contact: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

Inhalation: Remove person to fresh air and keep comfortable for breathing.

Skin Contact: Rinse skin immediately with plenty of water for 15-20 minutes.

Ingestion: If accidentally ingested, seek immediate medical attention. Rinse mouth. Do NOT induce vomiting unless told to do so by the poison control center or doctor. Do NOT give anything by mouth to an unconscious person.

DIRECTIONS FOR USE

CLEANING

Blood, other bodily fluids, and gels/lubricants must be thoroughly cleaned from ultrasound probes before reprocessing with Tristel ULT.

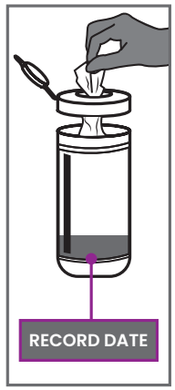
Dispose of blood and bodily fluids according to all applicable regulations for infectious waste disposal.

Refer to the ultrasound probes manufacturer's labeling and instructions for procedures on disassembly, handling, cleaning and decontamination.

OPENING AND SETTING UP THE TRISTEL ULT WIPES TUB AND TRISTEL ULT FOAM BOTTLE

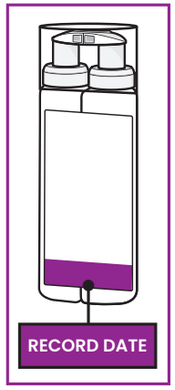
Opening and setting up the Tristel ULT Wipes tub

- Wear new gloves.
- Remove the lid of the tub and peel off the protective seal.
- Open the cap on the lid. Pull a wipe from the center of the roll and feed it through the dispenser hole within the lid.
- Secure the lid on the tub. Pull a couple of wipes to confirm that the wipes are dispensing. Discard dispensed wipes.
- Close the cap on the lid tightly. Ensure that the wipes are covered by the cap and the lid.
- Use Tristel ULT Wipes within 6 months after opening.
- Record the date the tub is opened and the 'Use by' date in the designated area on the tub label (front panel).
- Check that 'Use by' date does not extend past the expiration date. Expiration date is printed on the tub in the format YYYY-MM-DD. If the 6 months from opening extend beyond the expiration date, record the expiration date in the 'Use by' field.



Opening and setting up the Tristel ULT Foam bottle

- Wear gloves and safety glasses.
- Remove cap from the Tristel ULT Foam bottle.
- Depress the pump 4 times to prime and prepare for use. Dispensed foam can be flushed with water to drain or contained on a Tristel ULT Wipe and disposed to waste in accordance with local regulations. The pump is now ready for use.
- Use Tristel ULT Foam within 6 months after opening.
- Record the date the bottle is first used, i.e. opened, and the 'Use by' date in the designated area on the front label of the bottle.
- Check that 'Use by' date does not extend past the expiration date. Expiration date is printed on Tristel ULT Foam label in the format YYYY-MM-DD. If the 6 months from opening extend beyond the expiration date, record the expiration date in the 'Use by' field on the label.
- Tristel Test Strips may be used to check that the Tristel ULT Foam bottle is dosing accurately and the concentration of Tristel ULT is at or above the MRC. Refer to Tristel Test Strips User Guide. (Tristel Test Strips are supplied separately.)



HIGH LEVEL DISINFECTION OF PROBES AND TRANSDUCERS

STEP 1.

- Check the 'Use by' date on the Tristel ULT Foam bottle and the Tristel ULT Wipes tub. Do not use if out of date.
- Remember, if Tristel ULT Foam bottle is being used for the first time, the pump must be primed. Refer to the instructions for opening and setting up the Tristel ULT Foam bottle (page 3).
- ALWAYS USE ON A CLEANED DEVICE.
- Wear new gloves when handling Tristel ULT and medical devices.

STEP 2.

Pull **one Tristel ULT Wipe** out of the tub and close the cap tightly.

Use one wipe for each probe/transducer.

Note: Do not use a wipe if the cap on the lid was open and the wipe was exposed to environment. Discard this wipe and take a new one. It is important to close the cap on the lid after each use.

STEP 3.

Lay the Tristel ULT Wipe in the palm of your hand and apply **4 doses** of Tristel ULT Foam.

STEP 4.

Gently close hand around the wipe and wait for **10 seconds**. Do not squeeze.

STEP 5.

Wipe the probe to spread the foam using a massaging motion from one end of the probe to the other **4 times**. Cover the entire surface of the probe including shaft and handle.

Ensure all surfaces are covered and the probe is visibly wet. Pay particular attention to any crevices, ridges or indentations.

STEP 6.

After wiping, leave the probe undisturbed. Place the probe on a clean surface to avoid recontamination. Contact time for high level disinfection is **2 minutes**.

It is recommended that a timer is used to ensure the contact time of 2 minutes is observed.

Discard the used wipe to clinical waste, do not macerate. **Do not reuse**. Follow local procedures and policies for waste disposal.

STEP 7.

Use a clean Tristel ULT Wipe to **thoroughly remove residue** of Tristel ULT Foam.

Put on clean gloves. Pull one Tristel ULT Wipe out of the tub and close the cap tightly.

Wipe the probe once over. Pay particular attention to any crevices, ridges, or indentations.

Discard the used wipe to clinical waste. **Do not reuse**.

POST-PROCESSING HANDLING AND STORAGE OF REUSABLE DEVICES

If the disinfected probe is not immediately reused, store it in a manner that will protect and keep it from being re-contaminated. Refer to device manufacturer's instructions for additional storage and handling instructions.

THE TRISTEL CHEMISTRY AND MODE OF ACTION

Tristel ULT Foam is based on Tristel's proprietary chlorine dioxide (ClO_2) chemistry, a well-documented and highly effective biocide. It is comprised of two "precursor" solutions (termed Tristel ULT Base solution and Tristel ULT Activator solution), which are packaged separately within two reservoirs and secured together within a single dispenser pump.

When depressed, the pump dispenses these solutions in parallel at equal volumes, and the components of these solutions chemically react. This reaction generates ClO_2, which is the active germicidal ingredient. A mesher present in the applicator pump causes the formulation to be dispensed as a ready-to-use foam.

Tristel ULT Wipes are dry, non-woven, low-linting wipes specifically intended to apply Tristel ULT Foam on the surface of a medical device.

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.

MICROBIOCIDAL ACTIVITY

Tristel ULT is a high level disinfectant with a contact time of 2 minutes.
Tristel ULT inactivates Human papillomavirus (HPV) type 16 and type 18[1]. Tristel ULT is also efficacious against *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, Carbapenem resistant *Klebsiella pneumoniae* (CRKP), Extended-Spectrum beta-lactamase (ESBL) producing *Escherichia coli*, *Streptococcus agalactiae*, *Candida albicans*, Duck Hepatitis B virus (DHBV), and Human immunodeficiency virus (HIV).

To qualify Tristel ULT as a high level disinfectant, the solution passed the AOAC Sporicidal Activity Test in 12 hours at 20°C at the minimum effective concentration (MEC) of 80% v/v of the nominal concentration.

GENERAL INFORMATION ON MEDICAL DEVICE REPROCESSING

Choose a germicide with the level of microbiocidal activity that is appropriate for the reusable medical device. See the labeling for the reusable device or contact the device manufacturer for further instructions.

Select a germicide that is labeled for the appropriate germicidal level and is compatible with the reusable device.

For medical device classification the user should determine whether the reusable device to be reprocessed is a critical or semi-critical device. According to the Spaulding classification system, critical medical devices are devices that are introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and require to be STERILIZED between uses. Semi-critical devices are medical devices that come into contact with mucous membranes or non-intact skin and need high level disinfection as a minimum. A high level disinfectant is a germicide that inactivates all microbial pathogens, except a large number of bacterial endospores, when used according to the labeling.

References:

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;1–5. https://doi.org/10.1002/jmv.25666

MATERIAL AND DEVICE COMPATIBILITY

Tristel ULT has been tested on a large number of materials and found to be compatible after a total of 120 hours immersion study, with these materials:

- Acrylonitrile butadiene styrene (ABS)
- Methyl acrylonitrile butadiene styrene (M-ABS)
- Polyamide 6 (PA6)
- Polyamide 6.6 (PA6.6)
- Polybutylene terephthalate (PBT)
- Polybutylene terephthalate (PBT)/ Polycarbonate (PC) blend
- Polycarbonate (PC)
- Polycarbonate (PC)/ Acrylonitrile butadiene styrene (ABS)
- Polyether ether ketone (PEEK)
- Polyetherimide (PEI)
- Polyethylene – high density (HDPE)
- Polyethylene – low density (LDPE)
- Polyimide (PI)
- Polymethylpentene (PMP)
- Polyphenylsulfone (PPSU)
- Polypropylene copolymer (PPC)
- Polypropylene homopolymer (PPH)
- Polysulfone (PSU)
- Polytetrafluoroethylene (PTFE)
- Polyvinyl chloride – plasticized/flexible (PVC)
- Polyvinyl chloride – unplasticized/rigid (uPVC)
- FKM/FPM (Fluorocarbon rubber)
- Polyurethane (PU) – rigid, 95A
- Silicone rubber
- Thermoplastic polyurethane (TPE-U/TPU)
- Thermoplastic vulcanizate (TPE-V) – PP/EPDM
- Epoxy resin
- Epoxy resin (heat cured)
- Silicone adhesive
- Glass
- Stainless steel (304)
- Stainless steel (316L)

Materials testing showed that anodized aluminum, polyurethane elastomer 35A and polyurethane elastomer 90A are not compatible. If the device you intend to disinfect using Tristel ULT is known to contain these materials, contact device manufacturer or Tristel for device specific compatibility information. Note: Material sample testing may not reflect compatibility of Tristel ULT with the finished medical devices.

Tristel ULT has been tested with representative medical devices: Alpinion Medical, BD (Bard Access Systems, Inc.), 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, and Verathon are compatible with Tristel ULT.

⚠ Refer to the ultrasound probe manufactures' labeling, care cards, and user manuals to confirm Tristel ULT is listed as a compatible high level disinfectant for your ultrasound probe or transducer. The list of ultrasound probes compatible with Tristel ULT can be found on the Tristel website **https://tristel.com/us-en/products/tristel-ult** or by scanning the QR code.

CLEANING AGENT COMPATIBILITY

Tristel ULT is compatible with detergents that are low foaming and easily rinsed. Follow medical device manufacturers' recommendations on cleaning.

STORAGE CONDITIONS AND EXPIRATION DATE

Store Tristel ULT in its original containers at a temperature of 15-25°C (59-77°F) in a ventilated area out of direct sunlight. Once opened use Tristel ULT Foam and Tristel ULT Wipes within 6 months. Check that this does not extend past the expiration date. Expiration dates are found on the labels. Expiration dates are printed in the format YYYY-MM-DD.

Store away from children.

USER TRAINING

The user should be adequately trained in the decontamination and disinfection of semi-critical medical devices and in the handling of chemical germicides/high level disinfectants.

The user may request training on use of Tristel ULT by contacting Tristel and its sales representatives.

Visit **www.tristel.com/training** to complete the online training module.

EMERGENCY AND ADDITIONAL INFORMATION

For further safety information please refer to the Material Safety Data Sheet. Emergency information can be obtained from Tristel in the UK **+ 44 1638 721500**, from Parker Laboratories in the USA **1-800-631-8888** or a Tristel sales representative.

DISPOSAL INFORMATION

Check State and local disposal regulations.

To avoid waste, use all material in this container as directed. If waste cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by State or local governments or by industry). Do not reuse or refill container.

Recycle container if available, puncture and dispose of in a sanitary landfill, or by incineration.

HOW SUPPLIED

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

ADDITIONAL PRODUCTS SUPPLIED SEPARATELY

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

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