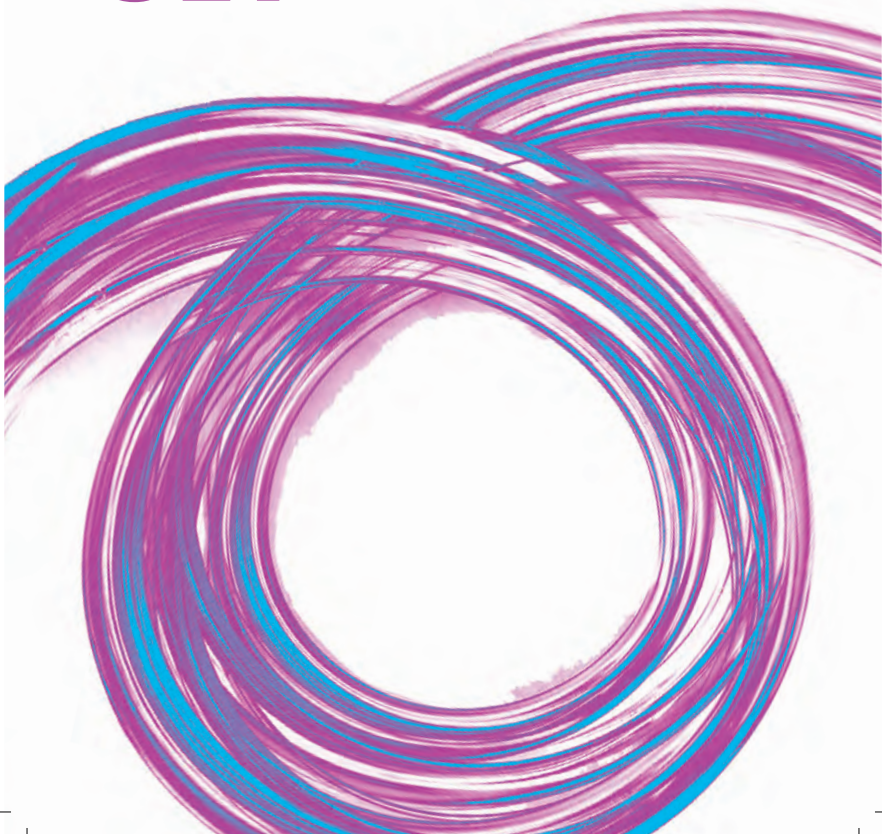


Tristel Duo™

ULT



Tristel Duo ULT is a chlorine dioxide based high-level disinfectant foam. It is CE marked as a Class IIb Medical Device (MDD 93/42 EEC).

INTENDED USE

Tristel Duo ULT is designed specifically for the high-level disinfection of endocavity ultrasound probes such as transrectal and transvaginal probes. Other uses include the high-level disinfection of non-invasive medical devices such as skin-surface probes (including those used during invasive procedures), bladder scanners and bladder pressure cuffs.

THE TRISTEL CHEMISTRY

Tristel Duo ULT is based on Tristel's proprietary chlorine dioxide (ClO₂) chemistry, a well-documented and highly effective biocide. Tristel Duo ULT incorporates two separate compartments that contain Tristel Base Solution (citric acid) and Tristel Activator Solution (sodium chlorite). When mixed upon pressing the foam pump, Tristel's proprietary chlorine dioxide chemistry is generated. Tristel Duo ULT contains a non-ionic surfactant for added cleaning performance.

BIOCIDAL PERFORMANCE

Tristel Duo ULT is sporicidal, mycobactericidal, virucidal, fungicidal and bactericidal with a contact time of 30 seconds. The product has been extensively tested according to all relevant European Standards required for disinfectants used in the medical area. Tristel Duo ULT is effective against microorganisms of concern such as:

- Human Papillomavirus (HPV)
- *Bacillus subtilis*
- *Clostridium difficile*
- *Mycobacterium terrae*
- Hepatitis B virus (HBV)
- Human Immunodeficiency Virus (HIV)
- Herpes Simplex Virus Type 1
- *Aspergillus brasiliensis*
- *Candida albicans*
- *Escherichia coli*
- *Neisseria gonorrhoeae*
- *Staphylococcus aureus*
- *Gardnerella vaginalis*
- *Streptococcus agalactiae*
- Carbapenem-resistant Enterobacteriaceae (CRE) *Klebsiella pneumoniae*
- Extended Spectrum- Beta-Lactamase (ESBL) *Klebsiella pneumoniae*
- Vancomycin-resistant Enterococci (VRE) *Enterococcus faecium*
- Methicillin-resistant *Staphylococcus aureus* (MRSA)

USER INSTRUCTIONS

- Do not use if the bottle is damaged.
- Disinfect hands and wear appropriate Personal Protective Equipment (PPE) when handling disinfectants and medical devices.
- If Tristel Duo ULT is used for the first time, depress the pump two to four times to prime it.
- Clean medical devices thoroughly prior to disinfection. Residual contamination with organic soiling, or ultrasound gel, will decrease the effectiveness of a disinfectant. Follow hospital protocol and medical device manufacturer's instructions.
- For professional use.
- These Instructions for Use (IFU) should be used in conjunction with the product label, Safety Data Sheet (SDS) and device manufacturer's instructions.

Step 1

Dispense two aliquots of Tristel Duo onto a dry wipe (Duo Wipe is recommended).

Step 2

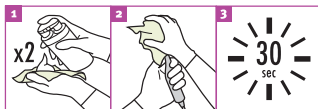
Use the wipe to spread the foam over the surface of the probe and ensure all areas are covered. Continuous wiping of the surface is not necessary and should be avoided to prevent shedding of the wipe. If required, use a cotton swab to spread the foam into indentations.

Note: Discard the used wipe in accordance with local regulations. Do not macerate. Do not re-use.

Step 3

Leave the surface to dry to ensure a minimum contact time of 30 seconds.

Note: Store the medical device in accordance with hospital protocols to prevent damage or recontamination.



Warning

Base

Causes serious eye irritation.



Precautionary statements

Base

Wear eye protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists:
Get medical advice.

Manufactured by: Tristel Solutions Ltd

For Tristel patent information please visit www.our-patents.info/tristel

Contact Tristel, your local distributor or visit www.tristel.com for supporting documents such as Safety Data Sheets, microbiological test data and reports.

Tristel™

WE HAVE CHEMISTRY.



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