

Tristel Duo™

OPH



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

INTENDED USE

Tristel Duo OPH is designed specifically for the high-level disinfection of medical devices used in ophthalmology such as diagnostic lenses, tonometer prisms, slit lamps, pachymeters, A-scan and B-scan biometry probes.

THE TRISTEL CHEMISTRY

Tristel Duo OPH is based on Tristel's proprietary chlorine dioxide (ClO₂) chemistry, a well-documented and highly effective biocide. Tristel Duo OPH 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 OPH contains a non-ionic surfactant for added cleaning performance.

BIOCIDAL PERFORMANCE

Tristel Duo OPH 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 OPH is effective against microorganisms of concern such as:

- *Acanthamoeba castellanii* (one of the causative organisms of *Acanthamoeba keratitis*)
- *Bacillus subtilis*
- *Clostridium difficile*
- *Mycobacterium terrae*
- Adenovirus Type 5
- Poliovirus Type 1
- Influenza A virus (H₁N₁)
- Hepatitis C virus (HCV)
- *Aspergillus flavus*
- *Aspergillus brasiliensis*
- *Fusarium solani*
- *Candida albicans*
- *Pseudomonas aeruginosa*
- *Enterococcus hirae*
- *Neisseria gonorrhoeae*
- *Staphylococcus aureus*
- Methicillin-resistant *Staphylococcus aureus* (MRSA)
- Carbapenem-resistant Enterobacteriaceae (CRE) *Klebsiella pneumoniae*
- Extended Spectrum- Beta-Lactamase (ESBL) *Klebsiella pneumoniae*
- Vancomycin-resistant Enterococci (VRE) *Enterococcus faecium*

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 OPH 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 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). Use the wipe to spread the foam over the surface of the medical device and ensure all areas are covered. Smaller devices can be placed directly into foam that has been dispensed onto the wipe. Continuous wiping of the surface is not necessary and should be avoided to prevent shedding of the wipe.

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

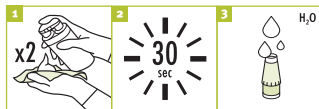
Step 2

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

Step 3

Rinse the medical device with water of appropriate quality.

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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