# Tristel **TRISTEL**

TRISTEL DUO OPH

Rapid and reliable high-level disinfection for ophthalmic devices.

Click here to start





# **CONTENTS**

About Tristel DUO OPH	04
We Have Chemistry	05
Why High Level Disinfect?	06
Exceptional Efficacy	07
Protect Your Patients Against Priority Pathogens	09
Protect Your Patients Against Priority Pathogens - AMR	11
Protect Your Patients Against Priority Pathogens - Biofilms	12
Compatibility	13
How to order	15

#### **Document controls**

Use the document controls located at the top of the pages to help you navigate through this brochure.





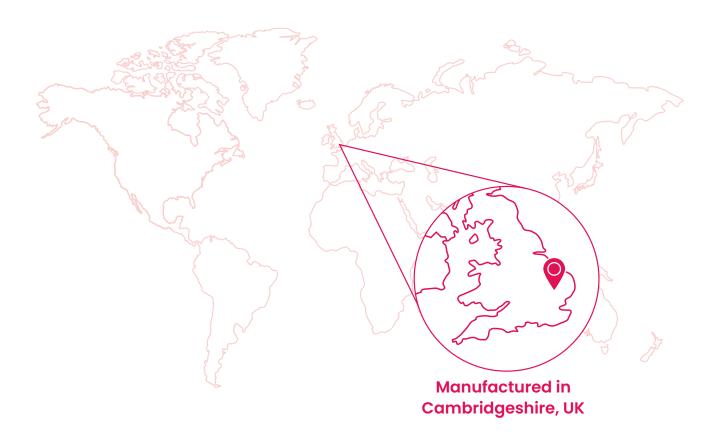






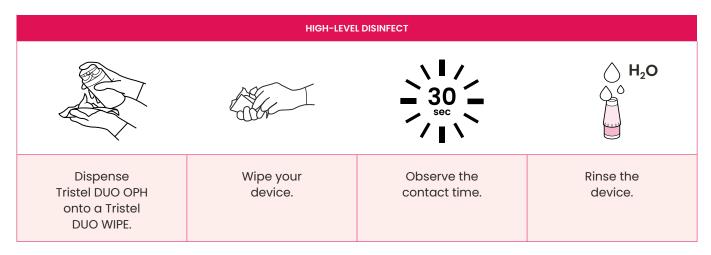


Tristel DUO OPH provides high-level disinfection of ophthalmic medical devices, such as diagnostic contact lenses, tonometer prisms, ophthalmic ultrasound probes and handheld pachymeters. Proven to be sporicidal, mycobactericidal, virucidal, fungicidal, yeasticidal and bactericidal in only 30 seconds, Tristel DUO OPH offers quick, effective and mobile protection against even the most difficult-to-eliminate microorganisms.



#### How does it work?

Tristel DUO OPH can be used with Tristel DUO WIPES for high-level disinfection of ophthalmic devices.





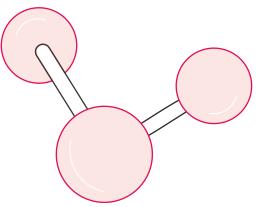
Refer to user guide for full instructions.







# **WE HAVE CHEMISTRY**



#### **Tristel Chlorine Dioxide**

Tristel's proprietary chlorine dioxide (CIO<sub>2</sub>) chemistry is trusted globally in healthcare settings for its fast-acting, easy-to-use and effective disinfection across diverse medical fields.

ClO₂ kills pathogens through electron exchange, stealing electrons from the microorganism's structures. Due to this reaction mechanism, microorganisms cannot develop resistance.

Tristel's chemistry is designed to work with innovative delivery systems to facilitate simple, but effective point of use disinfection, ensuring exceptional efficacy. Tristel's proprietary chlorine dioxide chemistry has a broad spectrum of biocidal efficacy and is proven effective against bacteria, bacterial spores, mycobacteria, enveloped and non-enveloped viruses, fungi and yeast.



**Broad Spectrum** 



**Fast** Acting



Ease of Use



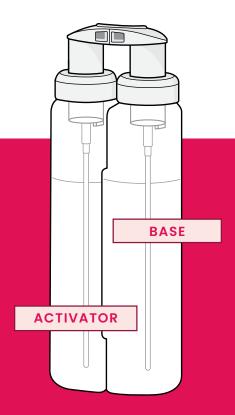
**Properties** 



**Prevents the Spread** of AMR Pathogens

> Tristel DUO **OPH** is free from alcohol and Quaternary **Ammonium Compounds** (QAC)

Tristel DUO OPH is simple: It has two separate compartments that contain 125ml of Tristel Base Solution (citric acid) and 125ml of Tristel Activator Solution (sodium chlorite). When the pump is pressed, the two solutions combine and chlorine dioxide chemistry is generated as a foam, ready to disinfect.









# WHY HIGH-LEVEL **DISINFECT?**

## **The Spaulding Classification**

Decontamination of medical devices is critical when it comes to preventing hospital acquired infections (HAIs), but why should you high-level disinfect ophthalmic devices?

The Spaulding Classification determines the appropriate level of disinfection (critical, semi-critical and non-critical) for medical devices, depending on the degree of risk of infection when used.1

All ophthalmic devices which come into contact with non-intact skin or mucous membrane should be high-level disinfected.

CATEGORY	DEVICE APPLICATION		REQUIRED LEVEL OF DISINFECTION
CRITICAL	Contact with the bloodstream or sterile tissues.	Surgical instruments, e.g. scalpels, tweezers, scissors, kidney dishes and clamps.	Sterilisation Eliminates all forms of microbial life.
SEMI-CRITICAL	Contact with mucous membranes or non-intact skin.	Contact lenses, tonometer prisms, ophthalmic ultrasound probes, handheld pachymeters.	High-Level Disinfection  Destroys all vegetative microorganisms, mycobacteria, enveloped and non-enveloped viruses, fungal spores and some bacterial spores.
NON-CRITICAL	Contact with	Ultrasound Probes which do not come into contact with non-intact skin or mucous membrane.	Intermediate-Level Disinfection Destroys mycobacteria, most viruses, most fungi and bacteria.
	intact skin.	Stethoscopes and blood pressure cuffs.	<b>Low-Level Disinfection</b> Destroys most bacteria, some viruses and some fungi.

Please note Tristel DUO OPH is a high-level disinfectant and is only suitable for the disinfection of semi-critical and non-critical devices.



# EXCEPTIONAL EFFICACY

# Effective in 30 seconds



Tristel DUO OPH is a high-level disinfectant, proven effective against a wide range of hard-to-kill microorganisms in **only 30 seconds**. All Tristel products are extensively tested according to relevant European tests such as those specified within the EN 14885.

STANDARD	ORGANISM TYPE	ORGANISM	TEST CONDITIONS
EN 17846	Bacterial Spores	Clostridioides difficile	Clean
			Dirty
EN 17126	Bacterial Spores	Bacillus subtilis	Clean
			Dirty
		Bacillus cereus	Clean
			Dirty
		Clostridioides difficile	Clean
			Dirty
	Mycobacteria	Mycobacterium terrae  Mycobacterium avium	Clean
EN 14348			Dirty
EN 14348			Clean
			Dirty
EN 14476	Viruses	Poliovirus  Adenovirus	Clean
			Dirty
			Clean
			Dirty
		Murine Norovirus	Clean
			Dirty
EN 13624	Fungi	Aspergillus brasiliensis	Clean
			Dirty
	Yeasts	Candida albicans	Clean
			Dirty

According to the acceptance criteria of the European standard: Bacterial spores, mycobacteria, fungi, yeast and viruses: 24 log<sub>10</sub> reduction. Bacteria: 25 log<sub>10</sub> reduction. Additional requirement for 4-field tests: F2-F4 <50 cfu/cm<sup>2</sup>









# **EXCEPTIONAL EFFICACY, CONTINUED**

STANDARD	ORGANISM TYPE	ORGANISM	TEST CONDITIONS
EN 16615	Yeasts	Candida albicans	Clean
			Dirty
	Bacteria	Staphylococcus aureus	Clean
			Dirty
		Pseudomonas aeruginosa	Clean
			Dirty
		Enterococcus hirae	Clean
			Dirty
EN 13727	Bacteria	Staphylococcus aureus	Clean
			Dirty
		Pseudomonas aeruginosa  Enterococcus hirae	Clean
			Dirty
			Clean
			Dirty

According to the acceptance criteria of the European standard: Bacterial spores, mycobacteria, fungi, yeast and viruses:  $^{24}$  log $_{10}$  reduction. Bacteria: ≥5 log<sub>10</sub> reduction. Additional requirement for 4-field tests: F2-F4 <50 cfu/cm<sup>2</sup>



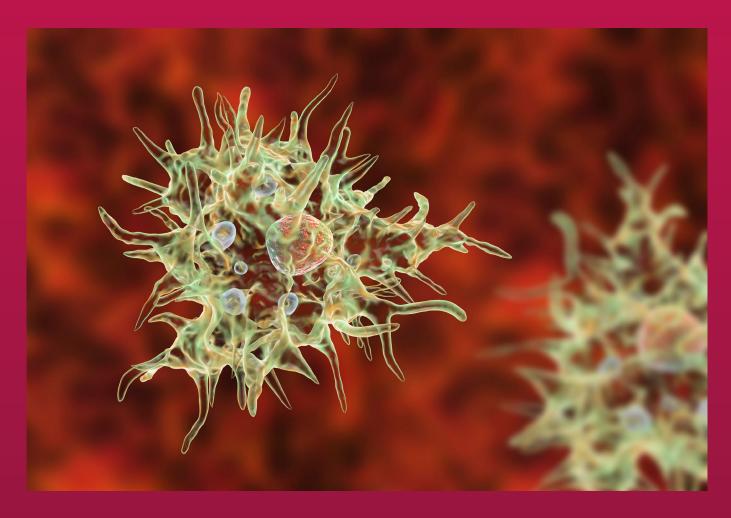


## **Against Priority Pathogens**

Ophthalmic devices are often exposed to potentially harmful microorganisms because they are used near or in direct contact with the eye's surface. This exposure elevates the risk of transmitting dangerous pathogens that may lead to serious infections such as conjunctivitis, keratitis, and endophthalmitis.

#### Acanthamoeba castellanii cysts

Acanthamoeba is a free-living amoeba frequently found in soil, water, and occasionally in contact lens solutions. Its cyst form is notably resistant to environmental stressors. The primary concern with this organism is its association with Acanthamoeba keratitis, a serious infection that occurs when amoeba infects the cornea. If left untreated, this condition can lead to significant eye damage and permanent vision loss.



Tristel DUO OPH has been tested for its effectiveness to eliminate *Acanthamoeba castellanii* cysts at an ISO 17025 accredited laboratory, where Tristel DUO OPH demonstrated a >3 log<sub>10</sub> reduction and a complete inactivation of *Acanthamoeba castellanii* cysts.







## **Against Priority Pathogens**

#### Tristel DUO OPH also effectively eliminates:



#### **Adenovirus**

The primary cause of viral conjunctivitis, accounting for approximately 65-95% of all cases.<sup>2</sup> Highly contagious, it can be transmitted through direct contact, contaminated surfaces and ophthalmic instruments used during eye examinations.



#### Neisseria gonorrhoeae

N. gonorrhoeae can cause
Gonococcal conjunctivitis
(GC), a serious condition that
can lead to complications
like blindness or systemic
infection. Approximately 10%
of neonates exposed to fluids
contaminated with
N. gonorrhoeae during
delivery may go on to
develop GC.4



#### Staphylococcus aureus

S. aureus is a common cause of ocular infections such as conjunctivitis, keratitis, and endophthalmitis.

Approximately 35% of the general public and 50–66% of hospital workers become colonised with S. aureus.6

#### Candida albicans

Candida species are among the most frequent microorganisms associated with fungal infections (candidiasis) such as keratitis and endophthalmitis, and candidemia. One study found that the incidence of ocular candidiasis in patients with candidemia ranged from 2-26%.<sup>7</sup>



#### Fusarium solani

Fusarium keratitis is a severe ocular infection, caused by the organism Fusarium solani, it is a common cause of monocular blindness. The annual prevalence of fungal keratitis is estimated to be over 1 million cases globally. Among these cases, Fusarium species is the most frequently isolated cause.<sup>7,8</sup>

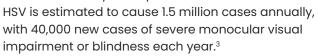


#### Pseudomonas aeruginosa

Globally, an estimated
10–15% of nosocomial
infections are due to
P. aeruginosa.
In addition, it is the most
identified causative organism
in contact
lens-related keratitis.<sup>5</sup>

#### Herpes simplex virus (HSV)

Can cause a range of diseases, including Herpes Simplex Keratitis (HSK), or ocular herpes, an infection that can lead to serious eye complications.







## **Against Priority Pathogens - AMR**

Antimicrobial resistance (AMR) is a critical global healthcare challenge, as microorganisms continue to evolve, rendering treatments for common infections less effective. This leads to increased healthcare costs, prolonged patient recovery times, and higher mortality rates.

Based on estimates across 204 countries and territories, new forecasts from the Global Research on Antimicrobial Resistance (GRAM) Project suggest that bacterial antimicrobial resistance (AMR) will cause 39 million deaths between 2025 and 2050 – which equates to three deaths every minute.

Tristel DUO OPH has been specifically tested against pathogens with known antibiotic resistance mechanisms, helping to prevent the spread of antimicrobial resistant organisms.

CIO<sub>2</sub> kills pathogens through electron exchange, stealing electrons from the microorganism's structures. **Due to this reaction mechanism microorganisms cannot develop resistance.** 

#### Tristel DUO OPH is effective in 30 seconds against:



Clostridioides difficile



Methicillin-resistant Staphylococcus aureus (MRSA)



Carbapenem-resistant Enterobacteriaceae (CRE) Klebsiella pneumoniae



Multidrug-resistant Acinetobacter baumannii (MDRAB)



Extended Spectrum Beta-Lactamase Klebsiella pneumoniae (ESBL)



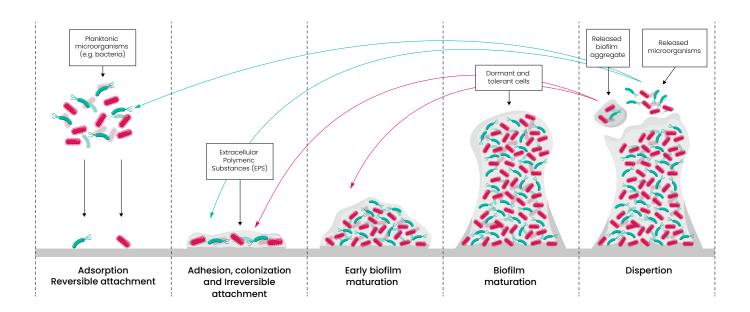
Vancomycin-resistant Enterococci (VRE) Enterococcus faecium

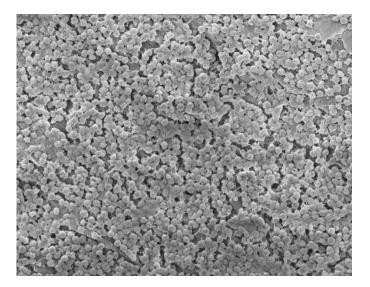


## **Against Priority Pathogens - Biofilms**

Biofilms are a significant issue in hospitals, they can provide a protective environment for microorganisms, allowing them to survive in harsh conditions, including exposure to disinfectants and antibiotics. These complex communities of microorganisms adhere to surfaces such as medical devices and general surfaces, making the microorganisms particularly difficult to eliminate.

Bacteria living in a biofilm exhibit a 10 to 1,000-fold increase in resistance to antibiotics compared to their planktonic counterparts.<sup>10</sup>





Biofilms can lead to persistent infections, increased resistance to treatments and a heightened risk of cross-contamination. Their presence on medical equipment, environmental surfaces and within environments such as water systems can also contribute to hospital-acquired infections (HAIs), posing a serious risk to patient safety.

It's estimated that around 65-80% of Hospital Acquired Infections are linked to biofilms.<sup>11,12</sup>

Tristel DUO OPH has been specifically tested for its efficacy against both wet and dry biofilms, ensuring your product is effective in these environments.



# COMPATIBILITY

## With Major Manufacturers

Tristel DUO OPH has been tested and proven to be compatible with the instruments of major manufacturers, including:

- DGH Technologies
- Ellex
- Haag-Streit
- Keeler Accutome
- Laboratoires Thea

- Natus Medical
- NeoLight /
   Phoenix Technology Group
- Nidel
- Ocular Instruments

- Quantel Medical
- Reichert Technologies
- Takagi
- Tomey
- Volk









# HOW TO ORDER

**Tristel DUO OPH** 

High-level

foam

disinfectant



#### **Tristel DUO WIPES**

Soft, durable, low-linting wipes

#### **Ordering information:**

Tristel DUO OPH
Pack of 6 x 250ml

Product Code: TSL022701

Product Code: TSL022707 NHSSC Code: FAL15586 Tristel DUO OPH Pack of 2 x 250ml

Product Code: TSL023901

Tristel DUO WIPES Pack of 6 x 200

Product Code: TSL031601

#### Additional products:

Tristel Pre-Clean Wipes Product Code: TSL030401 NHSSC Code: FAL510

Tristel CLEAN

Product Code: TSL023301

Tristel Rinse Wipes
Product Code: TSL030301
NHSSC Code: FAL581

Tristel DUO OPH is classified as Class IIa Medical Device according to UK MDR and EU MDR. Tristel DUO WIPES are classified as a Class I Medical Device according to UK MDR and EU MDR.



## REFERENCES

- CDC Infection Control (2008). A Rational Approach to Disinfection and Sterilization. [online] CDC Infection Control. Available at: <a href="https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/rational-approach.html#toc">https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/rational-approach.html#toc</a>
- Watson, S., Carbrera-Aguas, M. and Khoo, P. (2018). Common eye infections. pp.67–72. doi: <a href="https://doi.org/10.18773/austprescr.2018.016">https://doi.org/10.18773/austprescr.2018.016</a>.
- Farooq, A.V. and Shukla, D. (2012). Herpes Simplex Epithelial and Stromal Keratitis: An Epidemiologic Update. Survey of ophthalmology, 57(5), pp.448–462. doi :https://doi.org/10.1016/j. survophthal.2012.01.005.
- Costumbrado, J., Ng, D.K. and Ghassemzadeh, S. (2020).
   Gonococcal Conjunctivitis. [online] PubMed.
   Available at: <a href="https://www.ncbi.nlm.nih.gov/books/NBK459289/">https://www.ncbi.nlm.nih.gov/books/NBK459289/</a>.
- Gitter, A., Mena, K.D., Mendez, K.S., Wu, F. and Gerba, C.P. (2024). Eye
  infection risks from Pseudomonas aeruginosa via hand soap and
  eye drops. Applied and environmental microbiology.
  doi: <a href="https://doi.org/10.1128/aem.02119-23">https://doi.org/10.1128/aem.02119-23</a>.
- O'Callaghan, R. (2018). The Pathogenesis of Staphylococcus aureus Eye Infections. Pathogens, 7(1), p.9. doi: <a href="https://doi.org/10.3390/pathogens7010009">https://doi.org/10.3390/pathogens7010009</a>.
- Petrillo, F., Sinoca, M., Fea, A.M., Galdiero, M., Maione, A., Galdiero, E., Guida, M. and Reibaldi, M. (2023). Candida Biofilm Eye Infection: Main Aspects and Advance in Novel Agents as Potential Source of Treatment. Antibiotics, 12(8), p.1277. doi: https://doi.org/10.3390/antibiotics12081277.

- 8. Szaliński, M., Zgryźniak, A., Rubisz, I., Gajdzis, M., Kaczmarek, R. and Przeździecka-Dołyk, J. (2021). Fusarium Keratitis—Review of Current Treatment Possibilities. Journal of Clinical Medicine, 10(23), p.5468. doi: <a href="https://doi.org/10.3390/jcm10235468">https://doi.org/10.3390/jcm10235468</a>.
- Noel, D.J., Keevil, C.W. and Wilks, S.A. (2025). Development of disinfectant tolerance in Klebsiella pneumoniae. Journal of Hospital Infection, 155, pp.248–253. doi: <a href="https://doi.org/10.1016/j.ihin.2024.11.006">https://doi.org/10.1016/j.ihin.2024.11.006</a>.
- Naghavi, M., Vollset, S.E., Ikuta, K.S., Swetschinski, L.R., Gray, A.P., Wool, E.E., Robles Aguilar, G., Mestrovic, T., Smith, G., Han, C., Hsu, R.L., Chalek, J., Araki, D.T., Chung, E., Raggi, C., Gershberg Hayoon, A., Davis Weaver, N., Lindstedt, P.A., Smith, A.E. and Altay, U. (2024). Global Burden of Bacterial Antimicrobial Resistance 1990–2021: a Systematic Analysis with Forecasts to 2050. The Lancet, [online] 404(10459). doi: https://doi.org/10.1016/s0140-6736(24)01867-1.
- 11. Romeo, T. and Springerlink (Online Service (2008). Bacterial Biofilms. Berlin, Heidelberg: Springer Berlin Heidelberg.
- 12. Maillard, J.-Y. and Centeleghe, I. (2023). How biofilm changes our understanding of cleaning and disinfection. Antimicrobial Resistance and Infection Control, [online] 12(1), p.95. doi: https://doi.org/10.1186/s13756-023-01290-4

For more information on Tristel DUO OPH, please contact us:

mail@tristel.com

Scan for full efficacy data

