Tristel™

TRISTEL ULT COMBINATION PACK

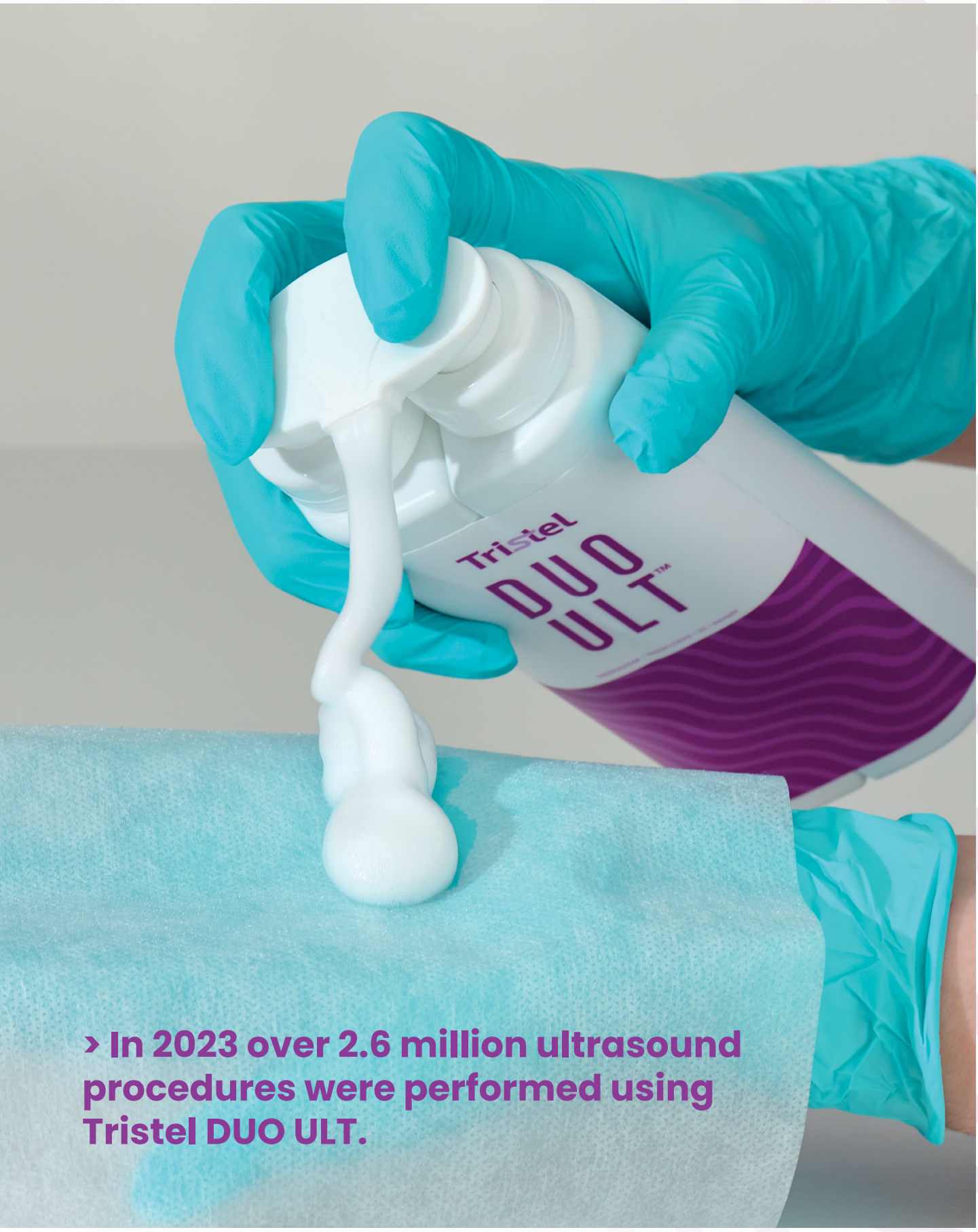
Complete - Compatible - Compliant

The **only** high-level disinfectant proven effective against HPV Types 16 & 18 in 30 seconds.

CONTENTS

Document controls

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



› In 2023 over 2.6 million ultrasound procedures were performed using Tristel DUO ULT.

Tristel DUO ULT provides high-level disinfection for endocavity ultrasound probes and skin surface transducers. Proven to be sporicidal, mycobactericidal, virucidal, fungicidal, yeasticidal and bactericidal in only 30 seconds, Tristel DUO ULT offers quick, effective and mobile protection against even the most difficult to eliminate microorganisms.

Complete
Ultrasound decontamination process

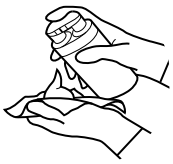
Compatible
With devices from major manufacturers

Compliant
With BMUS guidelines when used with 3T

Manufactured in Cambridgeshire, UK

How does it work?

Tristel DUO ULT foam is supplied within a combination pack, providing you with a full ultrasound decontamination procedure in one, convenient kit.

CLEAN	HIGH-LEVEL DISINFECT			TRACE
				
Use Tristel CLEAN with a DRY WIPE to clean your device.	Dispense Tristel DUO ULT onto a DRY WIPE.	Wipe your device.	Observe the contact time, no rinsing required.	Track your decontamination cycles with 3T.

Refer to user guide for full instructions.

WE HAVE CHEMISTRY

Tristel Chlorine Dioxide

Tristel's proprietary chlorine dioxide (ClO_2) chemistry is trusted globally in healthcare settings for its fast-acting, easy-to-use and effective disinfection across diverse medical fields.

ClO_2 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 and bacterial spores, mycobacteria, enveloped and non-enveloped viruses, fungi and yeast.

Broad Spectrum

Fast Acting

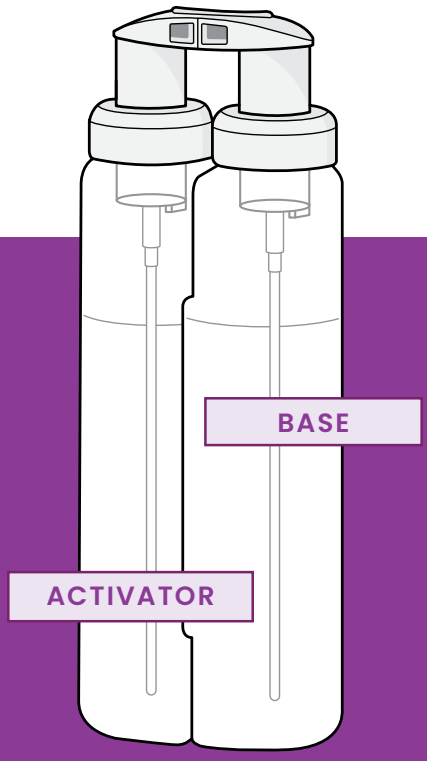
Ease of Use

Cleaning Properties

Prevents Antimicrobial Resistance (AMR)

› Tristel DUO ULT is free from alcohol and Quaternary Ammonium Compounds (QAC)

Tristel DUO ULT 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?

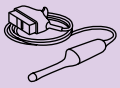
The Spaulding Classification

Decontamination of medical devices is critical when it comes to preventing hospital acquired infections (HAIs), but why should you high level disinfect endocavity ultrasound probes and skin surface transducers?

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]

The classification system does not account for instances where non-critical devices come into contact with blood from non-intact skin, or mucous membranes. Such exposure would require reclassification of the device, at a minimum, to semi-critical and ultimately require at a minimum, high-level disinfection.

Examples of this are: ultrasound vascular access procedures (for central line or IV placement), biopsies, or assessments where there is compromised skin/an open wound present.

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.	 Endoscopes and endocavity ultrasound probes.	**High-Level Disinfection** Destroys all vegetative microorganisms, mycobacteria, enveloped and non-enveloped viruses, fungal spores and some bacterial spores.
NON-CRITICAL	Contact with intact skin.	 Abdominal ultrasound probes.	**Intermediate-Level Disinfection** Destroys mycobacteria, most viruses, most fungi and bacteria.
		 Stethoscopes and blood pressure cuffs.	**Low-Level Disinfection** Destroys most bacteria, some viruses and some fungi.

Please note Tristel DUO ULT 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 ULT 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
EN 14348	Mycobacteria	*Mycobacterium terrae*	Clean
			Dirty
		Mycobacterium avium	Clean
			Dirty
EN 14476	Viruses	Poliovirus	Clean
			Dirty
		Adenovirus	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: ≥4 log_{10} reduction. Bacteria: ≥5 log_{10} reduction. Additional requirement for 4-field tests: F2-F4 <50 cfu/cm_2

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	Clean
			Dirty
		Enterococcus hirae	Clean
			Dirty

According to the acceptance criteria of the European standard: Bacterial spores, mycobacteria, fungi, yeast and viruses: ≥4 log_{10} reduction. Bacteria: ≥5 log_{10} reduction. Additional requirement for 4-field tests: F2-F4 <50 cfu/cm_2

PROTECT YOUR PATIENTS

Obstetrics and Gynaecology

Research conducted by Meyers et al., (2020) demonstrates Tristel DUO ULT is effective against infectious **HPV types 16 and 18**, on a transvaginal ultrasound probe in 30 seconds.

Tristel DUO ULT has also been extensively tested and proven to be vital in the prevention of infections within gynaecology and obstetrics. **It's effective in 30 seconds against:**

Virus

Human Papillomavirus (HPV) Type 16 and 18

HPV Types 16 and 18 cause approximately **70%** cases of cervical cancer.[2,3,4]

Bacteria

Gardnerella vaginalis (bacterial vaginosis (BV))

BV is prevalent in **23-29%** of women of reproductive age.[7]

Fungi/Yeast

Candida albicans

Candida albicans is responsible for **70%** global fungal infections, with a mortality rate of close to **40%** for invasive infections.[5]

Virus

Human Immunodeficiency Virus (HIV)

In 2023, an estimated **630,000** people died from HIV-related causes and estimated **1.3 million** acquired HIV.[8]

Bacteria

Neisseria gonorrhoeae (gonorrhoea)

There are an estimated **82 million** new cases of gonorrhoea per year.[6]

See The Data brochure for the full efficacy data.

PROTECT YOUR PATIENTS

In *In-Vitro* Fertilisation

With an average of four transvaginal ultrasound scans per IVF treatment course[9], you need to be confident in your high-level disinfectant. Tristel DUO ULT is an ideal disinfectant for use in in vitro fertilisation (IVF) settings.

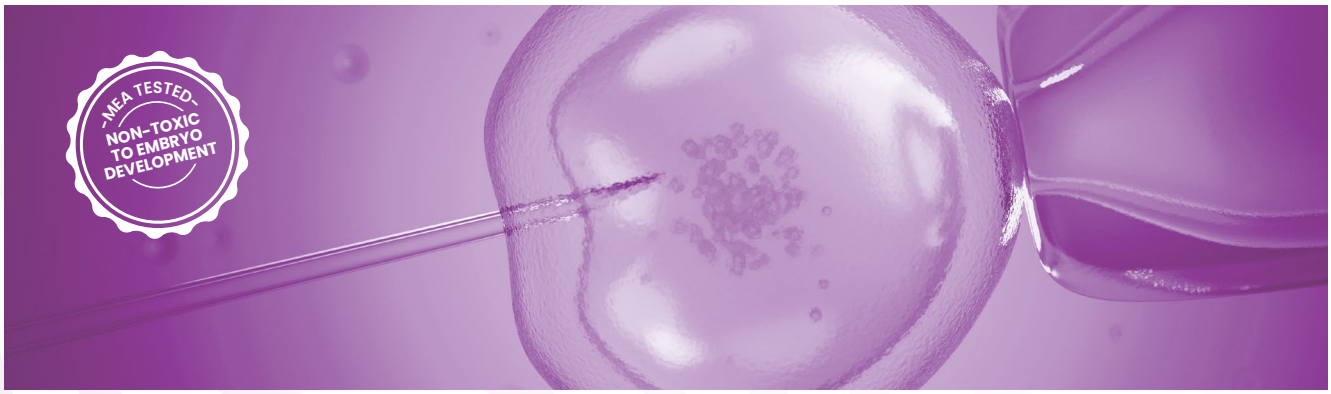
The Mouse Embryo Assay (MEA) evaluates the potential toxicity of the disinfectant by assessing its impact on embryo development.

The Sperm Motility Assay (SMA) determines the effect of the disinfectant on sperm motility and viability over time.

These tests ensure that exposure does not negatively impact sperm function, compromise viability, or hinder normal embryo growth.

Tristel DUO ULT has been specifically tested, and results confirm that the disinfectant is non-toxic to embryos and sperm in assisted reproduction settings.

See The Data brochure for the full efficacy data.



PROTECT YOUR PATIENTS

Against Priority Pathogens

Antimicrobial Resistance

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.**[10]

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

ClO_2 kills pathogens through electron exchange, stealing electrons from the microorganism's structures. Due to this reaction mechanism microorganisms cannot develop resistance.

Tristel DUO ULT effectively eliminates:

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*

See The Data brochure for the full efficacy data.

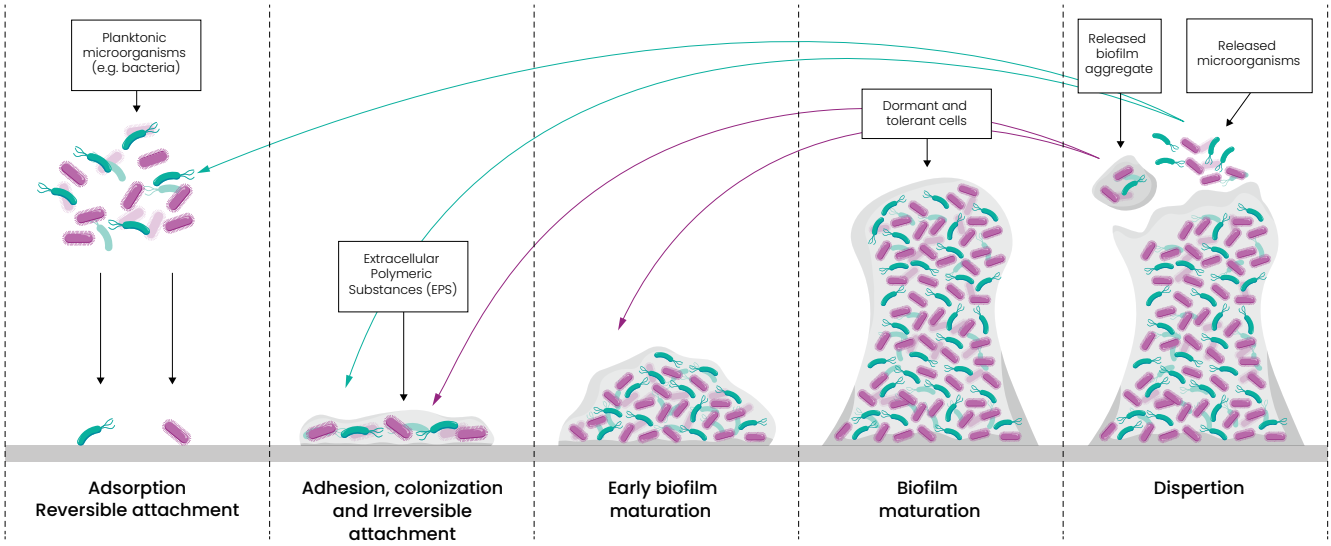
PROTECT YOUR PATIENTS

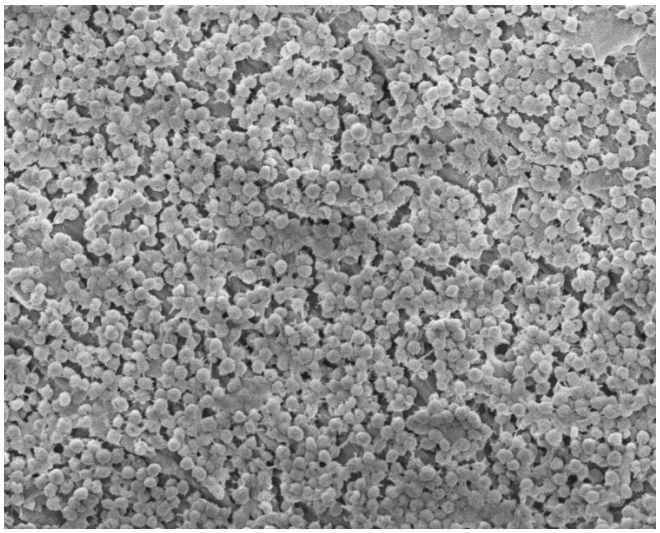
Against Priority Pathogens

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.[11]





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.[12,13]

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

See The Data brochure for the full efficacy data.

COMPATIBILITY

With Major Manufacturers

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

- Alpinion
- BD (Bard Access)
- BK Medical
- Butterfly Network
- Canon Medical Systems
- Carestream
- Esaote
- Exact Imaging
- FUJIFILM Healthcare
- FUJIFILM SonoSite
- GE Healthcare
- KOELIS
- Healcerion
- MCube
- Mindray
- MobileODT
- NIPRO CANADA
- Philips
- Quantel Medical
- Samsung Healthcare
- Siemens Healthineers
- Sonoscape
- Supersonic Imagine
- Verathon

Click here for compatibility checker

DIGITAL TRACEABILITY & TRAINING

Say goodbye to paper-based traceability

Complete
Cloud-based traceability and training platform

Compatible
With Tristel ULT Combination Pack

Compliant
Be compliant with guidelines by recording your decontamination procedures with 3T

Tristel DUO ULT is fully compatible with 3T, Tristel's cloud-based compliance platform, created to guide you through the Tristel ULT Combination Pack decontamination process and provide you with greater visibility on your infection control procedures.

Recording your Tristel ULT Combination Pack decontamination processes through 3T ensures you are fully compliant with BMUS guidelines.

Other features of 3T include:

- Product training and certifications
- Secure administration portal
- User-friendly and accessible dashboards
- Localisation and scan features

TRISTEL ULT COMBINATION PACK

What do I get?

Included in your Tristel ULT Combination Pack are **150 full decontamination procedures.**

Tristel CLEAN

Triple enzymatic medical device cleaning foam

Tristel DUO ULT

High-level disinfectant foam

Tristel DRY WIPES

Soft, durable, low-linting wipes

Ordering information:

Tristel ULT Combination Pack: 1 x Tristel CLEAN, 1 x Tristel DUO ULT, 1 x Tristel DRY WIPES
Product Code: TSL024701

Tristel DUO ULT combination pack is classified as a Class IIb Medical Device according to UKCA and EU MDR.
Tristel DUO ULT is classified as a Class IIb Medical Device according to UKCA and EU MDR.
Tristel CLEAN and DRY WIPES are classified as a Class I Medical Device according to UKCA and EU MDR.

REFERENCES

1. CDC Infection Control (2008). A Rational Approach to Disinfection and Sterilization. [online] CDC Infection Control. Available at: https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/rational-approach.html#toc

2. Burd, E.M. (2003). Human Papillomavirus and Cervical Cancer. Clinical Microbiology Reviews, [online] 16(1), pp.1–17. doi: https://doi.org/10.1128/cmr.16.1.1-17.2003.

3. World Health Organization (2024a). Cervical Cancer. [online] World Health Organization. Available at: https://www.who.int/news-room/fact-sheets/detail/cervical-cancer.

4. NHS Inform (2023). Cervical cancer symptoms and treatments. [online] www.nhsinform.scot. Available at: https://www.nhsinform.scot/illnesses-and-conditions/cancer/cancer-types-in-adults/cervical-cancer/.

5. Talapko, J., Juzbašić, M., Matijević, T., Pustijanac, E., Bekić, S., Kotris, I. and Škrlec, I. (2021). Candida albicans—The Virulence Factors and Clinical Manifestations of Infection. Journal of Fungi, 7(2), p.79. doi:https://doi.org/10.3390/jof7020079.

6. World Health Organization (2024). Sexually Transmitted Infections (STIs). [online] World Health Organization. Available at: https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis).

7. World Health Organization (2023). Bacterial vaginosis. [online] www.who.int. Available at: https://www.who.int/news-room/fact-sheets/detail/bacterial-vaginosis.

8. World Health Organization (2024b). HIV and AIDS. [online] World Health Organization. Available at: https://www.who.int/news-room/fact-sheets/detail/hiv-aids.

9. Robertson, I., Chmiel, F.P. and Cheong, Y. (2020). Streamlining follicular monitoring during controlled ovarian stimulation: a data-driven approach to efficient IVF care in the new era of social distancing. Human Reproduction. doi:https://doi.org/10.1093/humrep/deaa251.

10. 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. Ledwoch, K., Dancer, S.J., Otter, J.A., Kerr, K., Roposte, D., Rushton, L., Weiser, R., Mahenthiralingam, E., Muir, D.D. and Maillard, J.-Y. (2018). Beware biofilm! Dry biofilms containing bacterial pathogens on multiple healthcare surfaces; a multi-centre study. Journal of Hospital Infection, 100(3), pp.e47–e56. doi:https://doi.org/10.1016/j.jhin.2018.06.028.

13. 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 ULT and the Tristel ULT Combination Packs, please contact us:

mail@tristel.com