TECHNICAL **DATA SHEET**

Tristel Trio Wipe System

DESCRIPTION

Tristel Trio is a comprehensive solution for the decontamination of semi-critical, non-lumened medical devices. It combines cleaning, high-level disinfection and rinsing with traceability. This system allows you to decontaminate devices at the point of use, eliminating the need to send them to the Central Sterilisation Services Department (CSSD). Decontamination takes a matter of minutes, helping to improve patient throughput.

TECHNICAL SPECIFICATION

Quantity	Box of 3 x 50 wipes
Applications	Nasendoscopes Transoesophageal echocardiography probes (TOE/TEE) Endocavity transducers (transvaginal/ transrectal) Laryngoscopes Intubation endoscopes and rigid optics Manometry catheters Ophthalmic medical devices
Box Contents	50 x Pre-Clean Wipes 50 x Sporicide Wipes 50 x Rinse Wipes 1 x 100ml Bottle Activator Foam 1 x (Optional) Quality Audit Trial Record Book

FEATURES

- 3 stage decontamination
- Effective against a wide range of micro-organisms
- For non-lumened, non-critical medical devices
- Cleans and disinfects
- Refills available

Cleanroom Supplies Ltd, The Warehouse, Cumrew, Carlisle, Cumbria. CA8 9DD
Tel: + 00 44 (0)1768 896 800
Email: customerservices@cleanroomsuppliesltd.com
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Regulatory

The system provides complete instrument decontamination and conforms to the Medical Device Directive, and is CE marked and classified as follows:

The Tristel Pre-Clean Wipe is a Class I Medical Device

The Tristel Sporicidal Wipe, which includes the Tristel Activator Foam, is a Class IIb Medical Device

The Tristel Rinse Wipe is a Class I Sterile Medical Device It has been independently tested and meets the requirements set out by European Norms including EN 14885. Sporicidal efficacy according to EN 17126:2018 is also demonstrated.

The system passes local regulatory requirements for Australia and New Zealand.

It has received a licence from the Health Department of the People's Republic of China and approval from the Russian Ministry of Health for import and sales in the Russian Federation. Other approvals include Hong Kong, Israel, Turkey and Saudi Arabia.

Chemistry

The Sporicidal Wipe utilises Tristel's proprietary chlorine dioxide chemistry, a well-documented and highly effective biocide.

The Sporicidal Wipe is impregnated with a Base Solution (citric acid) and the Activator Foam is a dilute solution of sodium chlorite. When mixed upon applying the Activator Foam onto the Wipe and scrunching together, chlorine dioxide chemistry is generated.

Chlorine dioxide does not form hazardous by-products or halogenated compounds and all three Wipes and Activator Foam are classed as non-hazardous under the Classification, Labelling and Packaging Regulation (CLP).

Due to the way chlorine dioxide breaks down and destroys microorganisms, resistance cannot develop over time.

Compatibility

The system has been tested and proven to be compatible with the instruments of major manufacturers including GE Healthcare, Philips, Samsung, BK Medical, Canon, Siemens Healthiness, and Karl Storz. A full list of compatible medical devices can be provided on request.

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Efficacy

The activated Tristel Sporicidal Wipe is a high-level disinfectant and is proven effective against a wide range of microorganisms in 30 seconds, including:

- Human papillomavirus (HPV)
- SARS-CoV-2 (COVID-19)
- Bacillus subtilis
- Clostridium sporogenes
- Mycobacterium tuberculosis
- Mycobacterium avium
- Aspergillus brasiliensis
- Candida albicans
- Adenovirus
- Staphylococcus aureus
- Herpes Simplex Virus type 1

Human Papillomavirus (HPV)

HPV is a group of non-enveloped DNA viruses. There are 14 HPV types that are considered high-risk and are responsible for approximately 99% of cervical cancer cases and over 90% of oropharyngeal cancer cases. Research conducted by Meyers et al., (2020) demonstrates that the Tristel Sporicidal Wipe is effective against infectious HPV types 16 and 18, on a transvaginal ultrasound probe and a nasendoscope in 30 seconds.

SARS-CoV-2

SARS-CoV-2 is a severe acute respiratory syndrome virus and the strain of coronavirus responsible for the COVID-19 pandemic. Coronaviruses are a group of airborne viruses that spread via respiratory droplets. These droplets can be directly transmitted to a new host or indirectly via contaminated surfaces. Testing demonstrates that Tristel's proprietary chlorine dioxide chemistry is effective against SARS-CoV-2 in 30 seconds.

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Microbiological Test Reports

Organism Type	European Standard	Uniform Contact Time
Bacteria	EN 13727	**30 Seconds**
	EN 14561	
	EN 16615	
Yeasts/Fungi	EN 13624	
	EN 14562	
	EN 16615	
Viruses	EN 14476	
	EN 16615	
Mycobacteria	EN 14348	
	EN 14563	
Spores	EN 16615	
	EN 17126	

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User Guide

Applications of the Tristel Trio Wipes System include (but are not limited to) the decontamination of nasendoscopes, transoesophageal echocardiogram (TOE/ TEE) probes, transvaginal and transrectal ultrasound probes and other invasive ultrasound probes, non-invasive ultrasound probes (including those used during invasive procedures), laryngoscopes, intubation endoscopes, manometry catheters and ophthalmic devices.

Before Starting Decontamination:

Wear appropriate Personal Protective Equipment (PPE).
Do not use if the Wipe sachet is damaged or the Wipe is discoloured, damaged or dry.
Do not use the Activator Foam if the bottle is damaged.
Continuous wiping of the surface is not necessary and should be avoided to prevent shedding of the wipe.
For professional use only.
These Instructions for Use (IFU) should be used in conjunction with the product label, Safety Data Sheet (SDS) and medical device manufacturer's instructions.
Do not use past the expiry date. For the expiry date and LOT number please see the surface of the carton.

STEP 1

The first step in the decontamination procedure of medical devices is cleaning of the surface to remove soiling and organic matter prior to high-level disinfectant. The Pre-Clean Wipe is impregnated with a triple-enzymatic detergent and surfactant.

1. Disinfect hands and wear gloves when handling disinfectants and medical devices.
2. Take one Pre-Clean Wipe sachet.
3. Remove the wipe from its sachet and lay it out in the palm of your hand.
4. Wipe the surface of the medical device until soiling and organic matter have been visibly removed. In case of heavy soiling, more than one wipe may be used.
5. Discard the used wipe and glove in accordance with local regulations. Do not reuse.

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STEP 2

The second step in the decontamination procedure is high-level disinfection. The Sporicidal Wipe, combined with the Activator Foam, create chlorine dioxide, a high-level disinfectant that eliminates micro-organisms from medical device surfaces.

6. Disinfect your hands and put on new gloves.
7. Take one Sporicidal Wipe sachet.
8. Remove the wipe from it's sachet and lay it out in the palm of your hand.
9. As soon as the wipe is removed from its sachet, remove the lid from the Activator Foam bottle and apply two aliquots of foam onto the wipe. Do not shake the activator foam bottle.
10. Fold the wipe in on itself and scrunch together for 15 seconds to activate. Ensure that the wipe is evenly covered with foam. Presence of a chlorine-like odour confirms that the wipe is ready to use.
11. Wipe the surface of the medical device in one movement to cover it with foam, ensuring all areas come into contact with the Wipe. Pay special attention to edges, ridges, indentations and areas where different materials connect.
12. Observe a 30-second contact time.
13. Discard the used Wipe in accordance with local regulations. Do not reuse.

STEP 3

The third and final step of the decontamination procedure is rinsing of the medical device. The rinse wipe is impregnated with de-ionised water and a low level of antioxidant, which removes chemical residue from a surface.

14. Take one Rinse Wipe sachet.
15. Remove the wipe from its sachet and lay it out in the palm of your hand.
16. Wipe the surface of the device that has been decontaminated to remove excess foam.
17. Discard the used Wipe and gloves in accordance with local regulations. Do not reuse.

Upon completion of the decontamination cycle the device should be left to air dry. Store the device in accordance with hospital protocols to prevent damage or recontamination.

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