Tristel Trio™

Wipes System

ENGLISH

INTENDED USE

The Tristel Trio Wipes System is a three-part system for the decontamination of non-lumened invasive and non-invasive medical devices. It comprises three Wipes and an Activator Foam that in sequence perform the steps of the decontamination procedure:

1. Cleaning with the Pre-Clean Wipe
2. High-level disinfection with the Sporicidal Wipe & Activator Foam
3. Rinsing with the Rinse Wipe

APPLICATIONS

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.

THE TRISTEL CHEMISTRY

The Sporicidal Wipe incorporates Tristel's proprietary chlorine dioxide (ClO_2) chemistry, a well-documented and highly effective biocide. The Wipe is impregnated with Tristel Base Solution (citric acid) and the Activator Foam is a dilute solution of sodium chlorite. When mixed upon applying Activator Foam onto the Sporicidal Wipe and scrunching them together, Tristel's proprietary chlorine dioxide chemistry is generated.

BIOCIDAL PERFORMANCE OF THE SPORICIDAL WIPE

The Sporicidal Wipe destroys organisms of concern such as bacterial spores, mycobacteria, viruses, fungi and bacteria in a contact time of 30 seconds. It has been extensively tested according to all relevant European Standards required for disinfectants used in the medical area. The Sporicidal Wipe is effective against microorganisms of concern such as:

- *Clostridium sporogenes*
- Human Papillomavirus (HPV)
- *Mycobacterium tuberculosis*
- Poliovirus Type 1
- Human Herpesvirus Type 1
- Adenovirus Type 5
- *Candida albicans*
- *Staphylococcus aureus*
- Vancomycin-resistant Enterococci (VRE) *Enterococcus faecium*
- *Klebsiella pneumoniae*
- *Escherichia coli*

USER INSTRUCTIONS

- Disinfect hands and wear gloves when handling disinfectants and medical devices.
- 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.
- If using the Tristel Quality Audit Trail Record Book, keep the empty Wipe sachets and Activator Foam bottle until the end of the decontamination procedure.
- 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 : CLEANING

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

The Pre-Clean Wipe is CE Marked as a Class I Medical Device (MDD 93/42 EEC).

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 soil 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 gloves in accordance with local regulations. Do not reuse. If using the Tristel Quality Audit Trail Record Book, keep the empty Wipe sachet for traceability.

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STEP 2 : ACTIVATING & HIGH-LEVEL DISINFECTING

CE 2797

The second step in the decontamination procedure is high-level disinfection of the medical device.

The Sporicidal Wipe is CE Marked as a Class IIb Medical Device (MDD 93/42 EEC).

6 Disinfect your hands and put on new gloves.

7 Take one Sporicidal Wipe sachet.

8 Remove the Wipe from its sachet and lay it out in the palm of your hand.

Note: *Activate the Sporicidal Wipe as soon as you have removed it from the sachet and use it immediately.*

9 Remove the lid from the Activator Foam bottle. Apply two aliquots of Activator Foam onto the Sporicidal Wipe.

Note: *If the Activator Foam bottle is being used for the first time, depress the pump two to four times to prime it. The first output from the foam bottle can be left on the Wipe, to be followed by complete aliquots. The Activator Foam bottle is then primed for subsequent use.*

10 Fold the Wipe in on itself and scrunch together **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.

Use the activated Wipe immediately.

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. If using the Tristel Quality Audit Trail Record Book, keep the empty Wipe sachet for traceability.

STEP 3 : RINSING

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The third and final step in 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 residues from a surface.

Each Rinse Wipe sachet is packed and then sterilised by gamma-irradiation.

The Rinse Wipe is CE Marked as a Class I Sterile Device (MDD 93/42 EEC).

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. If using the Tristel Quality Audit Trail Record Book, keep the empty Wipe sachet for traceability.

Note: *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.*

STEP 4 : TRACEABILITY

The Tristel Trio Wipes System can include either paper-based or digital traceability.

- The Tristel Quality Audit Trail Record Book can be used to manually document the Tristel Trio Wipes System decontamination procedure.
- Tristel 3T is a digital traceability system comprising an online Portal for data management and reporting, and an App to record Tristel Trio Wipes System decontamination procedures. The 3T App features optional training videos for increased compliance.

Both traceability systems include guidance on how to complete the record process correctly.

Note: *Tristel 3T is subject to market availability.*

Pre-Clean Wipe
United Kingdom Patent Number: GB 2 413 765
International Patent Numbers: AU 2004 319251, CA 2565814, CN ZL 2004 80042982.5, EP 1 742 672, NZ 550 686, US 7,807,118, ZA 2006 9791
International Patent Applications Pending: IN 6254/DELNP/2006

Sporicidal Wipe
United Kingdom Patent Number: GB 2 404 337
International Patent Numbers: CN ZL 2004 80021541.7 EP 1 648 523
International Patent Applications Pending: IN 672/DELNP/2006 US 2006 0051387 A1

Rinse Wipe
United Kingdom Patent Number: GB 2 413 765
International Patent Numbers: AU 2004 319251, CA 2565814, CN ZL 2004 80042982.5, EP 1 742 672, NZ 550 686, US 7,807,118, ZA 2006 9791
International Patent Applications Pending: IN 6254/DELNP/2006
Manufactured by: Tristel Solutions Ltd

Traceability System
United Kingdom Patent Number: GB 2 413 765
International Patent Numbers: AU 2004 319251 CA 2,565,814 CN ZL 2004 80042982.5 EP 1 742 672 NZ 550 686 US 7,807,118 US 8,080,216 ZA 2006 9791
International Patent Applications Pending: IN 6254/DELNP/2006

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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The Trio Wipes System is classified under the Australian Register of Therapeutic Goods as a Class IIb medical device, AUST R number: 182843.

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