Tristel

Trio Wipes System

3-part decontamination system for non-lumened medical devices with **manual traceability**

User guide

1 Pre-Clean Wipe

The first step in the decontamination process of medical devices is the thorough pre-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, producing ultra-low surface tension for rapid cleaning.

The Pre-Clean Wipe is a Class I Medical Device carrying the CE mark in accordance with the European Medical Devices Directive 93/42/EEC and the 2007/47/ EC amendments thereto.

HOW TO USE THE PRE-CLEAN WIPE

Important information for all applications and uses:

- Do not use if the Pre-Clean Wipe sachet has been damaged.

Step 1
Ensure there is a divide between a clean and dirty area.

Step 2
Disinfect hands and wear gloves when handling disinfectants and medical devices.

Step 3
Take one Pre-Clean Wipe sachet.

Step 4
Tear the sachet, remove the wipe, unfold it and lay out in the palm of your hand.

Step 5
Thoroughly 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 have to be used).

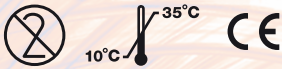
Step 6
Place the instrument back into the dirty area.

Step 7
Discard the wipe and gloves to clinical waste.

Traceability System
The Tristel Pre-Clean Wipe is incorporated into the Tristel Traceability System. Please complete the Tristel Traceability Book to keep record of the decontamination procedure.

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



3 Rinse Wipe

The final step in the decontamination process is the rinsing of the surface that has been treated with a chemical biocide. 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 a Class I Sterile Device carrying the CE mark in accordance with the European Medical Devices Directive 93/42/EEC and the 2007/47/ EC amendments thereto.

HOW TO USE THE RINSE WIPE

Important information for all applications and uses:

- Do not use if the Rinse Wipe sachet has been damaged.

Step 1
Take one Rinse Wipe sachet.

Step 2
Tear the sachet, remove the wipe, unfold it and lay out in the palm of your hand.

Step 3
Thoroughly wipe the surface of the device that has been decontaminated.

Step 4
Discard the wipe and gloves to clinical waste.

Traceability System
The Tristel Rinse Wipe is incorporated into the Tristel Traceability System. Please complete the Tristel Traceability Book to keep record of the decontamination procedure.

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

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

The Sporicidal Wipe is a Class IIb Medical Device carrying the CE mark in accordance with the European Medical Devices Directive 93/42/EEC and the 2007/47/EC amendments thereto.

MODE OF ACTION OF CHLORINE DIOXIDE

The Sporicidal Wipe incorporates Tristel's patented chlorine dioxide (ClO_2) chemistry, which is a powerful oxidising agent – an electron receiver. This means that the chlorine dioxide molecule is in constant search for an additional electron. When a bacterial cell comes into contact with chlorine dioxide, it donates an electron from its cell wall. This creates a breach in the cell wall through which contents pass in an attempt to bring the concentrations on either side of the cell membrane to equilibrium. The cell dies through lysis.

APPLICATIONS

Chlorine dioxide can kill all organisms, including spores, on a pre-cleaned medical device with a contact time of only 30 seconds. Examples of instruments that can be disinfected with the Sporicidal Wipe are nasendoscopes, transoesophageal echocardio probes, transvaginal and transrectal ultrasound probes, laryngoscope blades, intubation endoscopes, manometry catheters and instruments used in Ophthalmology.

The Sporicidal Wipe is far superior to a wipe that uses alcohol, a quaternary ammonium compound, a biguanide, chlorhexidine gluconate or any other available chemistry. The Sporicidal Wipe generates chlorine dioxide by applying Activator Foam onto the wipe. The foam contains a dilute solution of sodium chlorite. The wipe is impregnated with a blend of organic acids. Incorporated in the formulation is a buffering system that stabilises the pH at close to that of the skin mantle and an inhibitor system that protects sensitive materials.

The Sporicidal Wipe is patented (GB 2 404 337 B).

HOW TO USE THE SPORICIDAL WIPE

Important information for all applications and uses:

- The Sporicidal Wipe is only for use on non-lumened, heat sensitive, re-useable medical devices.

- Do not use if the Sporicidal Wipe sachet has been damaged.

- Pre-clean the surface of the medical device with the Pre-Clean Wipe before using the Sporicidal Wipe. As with all decontamination processes, thorough pre-cleaning of the surface to remove soil and organic matter is an essential first step.

Step 1

Disinfect hands and wear a new pair of gloves.

Step 2

Take one Sporicidal Wipe sachet.

Step 3

Tear the sachet, remove the wipe, unfold it and lay out in the palm of your hand.

Step 4

Take the lid off the Activator Foam bottle. If the Activator Foam bottle is being used for the first time, depress the pump two to four times to prime the foamer. The first output from the foam bottle can be left on the wipe, to be followed by two or four complete pumps*. The Activator Foam bottle is then primed for subsequent wipes.

* If you are using TRIO25, apply four measures of Activator Foam onto the Sporicidal Wipe.

If you are using TRIO50, apply two measures of Activator Foam onto the Sporicidal Wipe.

Step 5

Scrunch together 15 seconds to activate. Ensure that the wipe is evenly covered with foam. Presence of ‘chlorine like’ odour confirms that the wipe is ready to use.

Step 6

Wipe the surface of the medical device until it has been covered with Tristel. All areas of the surface must come into contact with the wipe at least once.

Step 7
Once the entire surface has been wiped and covered with Tristel, place the instrument in the clean area and wait 30 seconds.

Step 8
Dispose of the wipe to clinical waste.

REMEMBER

- Activate the Sporicidal Wipe as soon as you have removed it from the sachet and use it immediately.
- An activated wipe will have a faint odour of ClO_2.
- Rinse the surface after use of the Sporicidal Wipe.

Traceability System
Please complete the Tristel Quality Audit Trail Record Book to keep record of all decontamination procedures.

Sporicidal Wipe
United Kingdom Patent Number:
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International Patent Numbers:
CN ZL 2004 80021541.7
EP 1 648 523

International Patent Applications Pending:
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US 2006 0051387 A1

Traceability System
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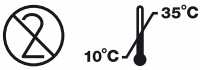

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