

The first step in the decontamination process of medical devices is the thorough cleaning of the surface to remove soil and organic matter prior to high-level disinfection.

The Tristel Pre-Clean Wipe is impregnated with a low-foaming surfactant system combined with triple enzymes, producing ultra-low surface tension for rapid cleaning. It is an effective means of performing the pre-cleaning stage of the decontamination process.

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

HOW TO USE THE TRISTEL PRE-CLEAN WIPE

For all applications and uses:

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

Step 1
Put on gloves.

Step 2
To dispense a wipe, take a sachet, tear and remove the wipe.

Step 3
Unfold the wipe and lay out on the palm of your hand.

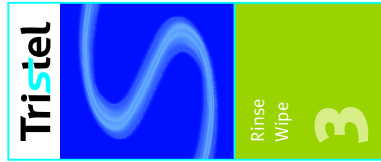
Step 4
Thoroughly wipe the surface until soil and organic matter have been visibly removed. (In cases of heavy soiling more than one wipe may have to be used).

Step 5
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: 2 413 765
International Patent Numbers:
AU 2004 309 251, CA 2 565 814, EP 1 742 672,
NZ 550 686, US 7,807,118, ZA 2006 9791
International Patent Applications Pending:
CN 2004,800429825, IN 62254/DELNP/2006



The final step in the decontamination process is the rinsing of the surface that has been treated by a chemical biocide.

The Tristel Rinse Wipe is impregnated with de-ionised water and a low-level of antioxidant which will remove and neutralize chemical residues from a surface that has been decontaminated with a Tristel Sporidical Wipe.

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

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

HOW TO USE THE TRISTEL RINSE WIPE

For all applications and uses:

Do not use if the Tristel Rinse Wipe Sachet has been damaged.

Step 1
Put on gloves.

Step 2
To dispense a wipe, take a sachet, tear and remove the wipe.

Step 3
Unfold the wipe and lay out on the palm of your hand.

Step 4
Thoroughly wipe the surface that has been decontaminated.

Step 5
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.

Manufactured by:
Tristel Solutions Limited
Lynx Business Park,
Fordham Road, Snailwell
Cambridgeshire CB8 7NY

Tel +44 (0)1638 721500
Fax +44 (0)1638 721911
Email mail@tristel.com
www.tristel.com

Rinse Wipe
United Kingdom Patent Number: 2 413 765
International Patent Numbers:
AU 2004 309 251, CA 2 565 814, EP 1 742 672,
NZ 550 686, US 7,807,118, ZA 2006 9791
International Patent Applications Pending:
CN 2004, 800429825, IN 62254/DELNP/2006

Australian sponsor:
AshMed Pty Ltd
Ground Level, 305 High Street
Prahran, VIC, 3181 Australia
Tel +61 6 0221 0345
Email info@ashmed.com.au



Tristel

Trio

Tristel Wipes System

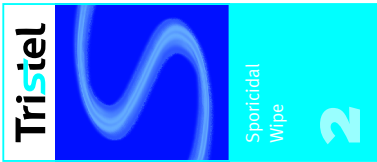
Pre-Clean Wipes

Sporidical Wipes

Rinse Wipes



User Guide



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

The Tristel Sporidical Wipe incorporates Tristel's patented chlorine dioxide (ClO₂) chemistry. It can kill all organisms on a pre-cleaned surface, from which soil and organic matter have been removed, with a contact time of only 30 seconds. The Tristel Sporidical Wipe is sporicidal, mycobactericidal, bactericidal, virucidal and fungicidal.

This means that non-lumened medical instruments that cannot be sterilised by heat, can now be decontaminated easily, quickly and safely. Examples of such instruments are nasendoscopes, transoesophageal probes, transvaginal and transrectal ultrasound probes, and GI manometry catheters. The Tristel Sporidical Wipe is not intended for use on critical medical devices which must be sterilised prior to use on a patient.

Biocidally, the Tristel Sporidical Wipe is far superior to a wipe that uses alcohol, a quaternary ammonium compound, a biguanide, chlorhexidine gluconate or any other available chemistry.

The Tristel Sporidical Wipe generates chlorine dioxide by applying foam to the surface of the wipe. The foam contains a dilute solution of sodium chlorite. The wipe is impregnated with a blend of organic acids, preservatives, buffers and corrosion inhibitors. The Tristel Sporidical Wipe is patented. (GB 2 404 337 B).

An almost instantaneous reaction generates a controlled level of chlorine dioxide in aqueous solution that is contained within the foam and the wipe. Chlorine dioxide is a powerful oxidising agent and is rapidly effective against all micro-organisms, including spores. Incorporated in the Tristel technology is a buffering system that stabilises the pH at close to that of the skin mantle and an inhibitor system that protects sensitive materials.

Important Information

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

HOW TO USE THE TRISTEL SPORICIDAL WIPE

For all applications and uses:

- Do not use if the sachet and/or foam bottle have been damaged.
- Pre-clean the surface before using the Tristel Sporidical Wipe. As with all decontamination processes, thorough pre-cleaning of the surface to remove soil and organic matter is an essential first step. The Tristel Pre-Clean Wipe can be used to pre-clean the surface of the medical device.

Step 1

Put on gloves.

Step 2

To dispense a wipe, take one sachet, tear and remove one wipe.

Step 3

Unfold the wipe and lay out on the palm of your hand.

Step 4

Take the lid off the foam bottle. Note that the foam bottle label is identified as ACTIVATOR FOAM. If the 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 complete pumps. The foam bottle is then primed for subsequent wipes.

For all subsequent wipes, pump two measures of Tristel Activator Foam onto the wipe.

When using a 50ml Activator Foam bottle pump four measures of foam onto the wipe.



Step 5

Scrunch the wipe for 15 seconds. Ensure that it 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.

Step 7

Once the entire surface has been wiped and covered with Tristel, wait **30 seconds**.

Step 8

Discard the wipe to clinical waste.

- Remember, activate the wipe as soon as you have removed it from the sachet and use it immediately. An activated wipe will have a faint odour of ClO₂.

- Rinse the surface after use of the Tristel Sporidical Wipe:

Following decontamination of a re-useable medical device with a Tristel Sporidical Wipe, the device should be thoroughly rinsed with water of appropriate quality before storage or re-use on the next patient. Tristel Rinse Wipe can be used.

If the surface decontaminated is not that of an invasive medical device, or is not re-useable, there is no need to rinse with water.

Please see overleaf for instructions on use of Rinse Wipes.

Traceability System

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

The Tristel Sporidical Wipe is a Class I/b medical device carrying the CE mark in accordance with the European Medical Device Directive 93/42/EEC and the 2007/47/EC amendments thereto.

Sporidical Wipes

United Kingdom Patent Number: 2 404 337

International Patent Numbers: AU 2004 319251, CA 2565814, EP 1 648 523

International Patent Applications Pending: IN 672/DELNP/2006, US 2006 0051387 A1

Traceability System

United Kingdom Patent Number: 2 413 765

International Patent Numbers: AU 2004 319251, CA 2565814, EP 1 742 672, NZ 550 686, US 7 807 118, ZA 2006 9791

International Patent Applications Pending: CN 2004 800429825, IN 6254/DELNP/2006

