TRISTEL DUO ULT MEETS THE REQUIREMENTS OF EN 14885:2018

FOR INTRACAVITY ULTRASOUND PROBES

Intracavity ultrasound probes are used to examine the female reproductive organs, the rectum and nearby structures, including the prostate. They are semi-critical medical devices and require high-level disinfection. All high-level disinfectants must be supported by a **complete set of efficacy claims** as required by EN 14885:2018 "Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics".

Each claim must be supported by microbiological efficacy testing by an accredited laboratory. To safeguard patient safety, the contact time and concentration of the product tested must be the same as that for which the product is labelled for use.

THE CONTACT TIME FOR TRISTEL DUO ULT IS 30 SECONDS.

Due to where intracavity ultrasound probes are used, they risk transmitting pathogens that are associated with sexually transmitted infections (STI) to patients and healthcare workers. The high-level disinfectant used for an intracavity probe must be bactericidal, yeasticidal, fungicidal, virucidal, mycobactericidal and meet requirements of the latest sporicidal test EN 17126[1], and it should also be proven to be effective against a wide range of STI pathogens to safeguard the patient.

IMPORTANT STIs AND VIRUSES THAT TRISTEL DUO ULT HAS BEEN TESTED AND PROVEN EFFECTIVE AGAINST INCLUDE:

- *Neisseria gonorrhoea* (Gonorrhoea)
- *Candida albicans* (Candida)
- *Gardnerella vaginalis* (Bacterial vaginosis)
- Human Immunodeficiency Virus (HIV)
- Hepatitis B virus (HBV)
- Herpes Simplex Virus
- Hepatitis C virus (HCV)
- **Human papillomavirus (HPV)**

HPV is of special concern. Serotypes 16 and 18 of this small, non-enveloped virus are extensively documented to be the causative agents of cancer of the cervix and of the head and the neck. They also play an important role in anogenital and oropharyngeal cancers.

Not all the high-level disinfectants included in The World Federation of Ultrasound in Medicine & Biology (WFUMB) (2017)[2] decontamination guidelines for transvaginal ultrasound transducers demonstrate effectiveness against HPV types 16 and 18.

Tristel Duo ULT is recognised as a high-level disinfectant in the WFUMB guidelines and has also been proven to be effective against HPV types 16 and 18 in studies undertaken in 2017 by Dr. Craig Meyers, of Penn State Hershey Medical Center[4]. His work involved suspension and carrier tests using the published protocol developed by him. This was employed in the work published by Dr. Craig Meyers and his team in the Journal of Medical Virology[3] comparing Cidex OPA and sonicated hydrogen peroxide. In this study, Cidex OPA was found to be ineffective against HPV type 16 and 18, whilst sonicated hydrogen peroxide was found to be effective.

More recent work has been conducted by Dr. Craig Meyers testing Tristel Duo ULT on an intracavity ultrasound probe representing a significant advance on earlier work involving sonicated hydrogen peroxide and UVC radiation. This work only used carrier based test methods. Dr. Craig Meyer's ground-breaking work is intended for peer-review and publication.

Notes:

1 EN 17126:2018 – *Bacillus cereus* >4 log reduction 30 seconds; *Bacillus subtilis on test*

2 Abramowicz et al (2017), GUIDELINES FOR CLEANING TRANSVAGINAL ULTRASOUND TRANSDUCERS BETWEEN PATIENTS. *Ultrasound in Medicine and Biology*, **43** (5): 1076-1079

3 Meyers J, Ryndock E, Conway MJ, Meyers C, Robison R. Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants. *J Antimicrob Chemother.* 2014;69(6):1546-50. doi: 10.1093/jac/dku006

4 Test reports available upon request

Tristel™

Created by: Tristel Solutions Limited, Lynx Business Park, Cambs, UK, CB8 7NY
T +44 (0) 1638 721500 - **E** mail@tristel.com - **W** www.tristel.com

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Tristel Duo™ ULT