Tristel Trio™

Wipes System

THE WORLD'S MOST WIDELY APPROVED, VALIDATED AND USED HIGH-LEVEL DISINFECTION WIPES SYSTEM FOR LARYNGOSCOPE BLADES

Within emergency care every second counts. Which is why we created the Tristel Trio Wipes System to be quick and mobile, for use in emergency rooms and rescue vehicles.

Tristel Trio™
Wipes System

THE TRISTEL TRIO WIPES SYSTEM IS EASY TO TRANSPORT & USE!

CLEAN
Tristel Pre-Clean Wipe

A non-woven wipe impregnated with a triple enzymatic detergent and surfactant used for a thorough cleaning of the medical device's surface to remove soil and organic matter.

HIGH-LEVEL DISINFECT
Tristel Sporicidal Wipe

This wipe combines with the Tristel Activator Foam to generate chlorine dioxide, a highly effective biocide that eliminates bacteria, viruses, fungi, mycobacteria and spores from the surface of the medical device in 30 seconds.

RINSE
Tristel Rinse Wipe

A sterile packed, non-woven wipe impregnated with deionised water and a low antioxidant content; used to remove any remaining chemical residues from the surface of the medical device.

TRACE
Tristel 3T or the Quality Audit Trail Record Book

Intended for the simple registration of all steps of the process, including validation by the responsible person.

CE Tristel Pre-Clean Wipe
Class I Medical Device

CE 2797 Tristel Sporicidal Wipe
Class IIb Medical Device

CE 2797 Tristel Rinse Wipe
Class I Sterile Device
STERILE R

QUICK

The Tristel Trio Wipes System provides a full decontamination cycle, including traceability, in a matter of minutes.

MOBILE

The Tristel Trio Wipes System is portable and requires no electricity or water to use. This enables it to be easily used in both the emergency room or in rescue vehicles.

COMPATIBLE

The Tristel Trio Wipes System has been tested and confirmed to be compatible with medical devices from the leading laryngoscope manufacturers, including:

- Airtraq*
- Medtronic
- Karl Storz
- Verathon

* Compatible with the Tristel Sporicidal Wipe as part of the Tristel Trio Wipes System

UNRIVALLED EFFICACY

The Tristel Sporicidal Wipe is proven effective as a high-level disinfectant according to EN 14885:2018 and the latest efficacy standards published, in 30 seconds. The product's fast-acting and uniform contact time leaves no room for doubt or error.

SMART TRACEABILITY

The Tristel Trio Wipes System includes either paper-based or digital traceability. The widely-used Quality Audit Trail Record Book documents each disinfection event with pen and paper. Tristel 3T digitalises this process for a more efficient, accurate and smart approach to traceability.

SIMPLE

Training and certification is an essential part of customer service with Tristel. Our Online Training Portal provides Tristel Trio Wipes System user training at a time and place convenient to you.

The Tristel Trio Wipes System offers complete decontamination of laryngoscope blades. Thanks to the concept of cleaning, high-level disinfection and rinsing, a validated result is achieved with a simple and fast three-step process.

Microbiological Testing

	Microbes Including	Uniform Contact Time
Bacteria	MRSA, VRE, *Klebsiella pneumoniae, Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae*	30 sec
Yeasts/ Fungi	*Candida albicans and auris, Aspergillus brasiliensis*	
Viruses	HPV, HBV, HCV, HIV, Herpes Simplex virus, Norovirus, Adenovirus, Poliovirus	
Mycobacteria	*Mycobacterium tuberculosis* (TB), *Mycobacterium avium*	
Spores	*Bacillus subtilis, Bacillus cereus, Clostridium sporogenes*	

TRISTEL TRIO WIPES SYSTEM

- Available in 5* or 50 decontamination procedure packs, with or without the Quality Audit Trail Record Book.

  Tristel 3T is sold separately.

LARYNGOSCOPE BLADE TRANSPORTATION

Tristel protect bags are designed specifically for the transportation and short-term storage (up to 72 hours) of medical devices, with traceability in mind.

TRISTEL PROTECT

- 50 bags per box.
- Available in small (21cm x 34cm) for laryngoscope blades

*Subject to market availability. More information about the Tristel Trio Wipes System, such as safety data sheets, reports, publications on materials and studies, is available on request or online at **www.tristel.com**.*

Tristel™
WE HAVE CHEMISTRY.

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For Tristel patent information please visit: http://www.our-patents.info/tristel

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Sporicidal Wipes

30 sec

Microbiological Efficacy Summary

Testing performed in accordance with EN 14885:2018
and the latest regulatory efficacy requirements for disinfectants used in the medical area

	ORGANISM	TEST NORM	TEST TYPE	CONDITIONS
SPORICIDAL	*Bacillus cereus*	EN 17126	Suspension	Clean 1
	Bacillus subtilis			
MYCOBACTERICIDAL	*Mycobacterium terrae*	EN 14563	Carrier	Clean 1 and Dirty 3
	Mycobacterium avium			
	Mycobacterium terrae	EN 14348	Suspension	Clean 1
	Mycobacterium avium			
VIRUCIDAL	Poliovirus Type 1	EN 14476	Suspension	Clean 1
	Adenovirus Type 5			
	Murine Norovirus			
FUNGICIDAL/ YEASTICIDAL	*Candida albicans*	EN 16615	Surface with mechnical action	Clean 1
	Candida albicans	EN 14562	Carrier	Clean 1 and Dirty 4
	Aspergillus brasiliensis	EN 13624	Suspension	Clean 1 and Dirty 1
	Candida albicans			Clean 1 and Dirty 4
BACTERICIDAL	*Staphylococcus aureus*	EN 16615	Surface with mechnical action	Clean 1
	Enterococcus hirae			
	Pseudomonas aeruginosa			
	Staphylococcus aureus	EN 14561	Carrier	Clean 1 and Dirty 4
	Enterococcus hirae			
	Pseudomonas aeruginosa			
	Staphylococcus aureus	EN 13727	Suspension	Clean 1 and Dirty 4
	Enterococcus hirae			
	Pseudomonas aeruginosa			

Additional Testing

	ORGANISM	TEST NORM	TEST TYPE	CONDITIONS
SPORES	*Clostridium sporogenes*	EN 14561 / AOAC 966.04	Carrier	Dirty 3
	Bacillus subtilis	Bespoke Wiping Test	Surface	Not applicable
	Bacillus subtilis	Bespoke Wiping Test	Surface	Dirty 1
	Bacillus cereus	EN 16615	Surface with mechnical action	Clean 1
MYCOBACTERIA	*Mycobacterium avium*	Bespoke Wiping Test	Surface	Dirty 1
	Mycobacterium terrae			
	Mycobacterium tuberculosis			
	Mycobacterium terrae	Griffiths et al. Journal of Hospital Infection (1998)	Suspension	Not applicable
VIRUSES	Human Papillomavirus Type 16	Bespoke Testing	Simulated In-use Test on Device	Dirty 3
	Human Papillomavirus Type 18			
	Hepatitis B Virus (HBV)	Bespoke Testing	Suspension	Not applicable
	Hepatitis C Virus (HCV)			
	Human Immunodeficiency Virus (HIV)			
	Poliovirus Type 1	ASTM E-1053	Surface	Dirty 3
	Herpes Simplex Virus Type 1			
	Poliovirus Type 1	DVV/RKI	Suspension	Clean 2 and Dirty 2
	Adenovirus Type 5			
	Polyoma virus SV40			
	Vaccinia Virus			
	Murine Norovirus	EN 16615	Surface with mechnical action	Clean 1
FUNGI/ YEAST	*Aspergillus brasiliensis*	EN16615	Surface with mechanical action	Clean 1
	Trichophyton interdigitale	AOAC 955.17	Carrier	Dirty 3
BACTERIA	*Escherichia coli*	EN 14561	Carrier	Clean 1 and Dirty 4
	Enterobacter cloacae			Clean 1
	Vancomycin Resistant Enterococci (VRE) *Enterococcus faecium*			
	Klebsiella pneumoniae			
	Methicillin-resistant *Staphylococcus aureus* (MRSA)	EN 13727	Suspension	

Clean/Dirty Conditions Key:

Clean 1: 0.3 g/l bovine albumin - **Clean 2:** Aqua bidest

Dirty 1: 3g/l bovine albumin - **Dirty 2:** 10% fetal calf serum - **Dirty 3:** 5% fetal bovine serum - **Dirty 4:** 3g/l bovine albumin 3g/l blood erythrocytes

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Tristel Trio™ Wipes System

Publication Summaries

Disinfection of intracavity ultrasound transducers: ASA practice update.
Approved by the ASA Board of Directors March 2018.
To be reviewed 2020.

The Australasian Sonographers Association (ASA) advises all members that disinfection of intracavity ultrasound transducers must meet relevant recognised standards, as described below. This applies to all intracavity transducers, such as those used for:

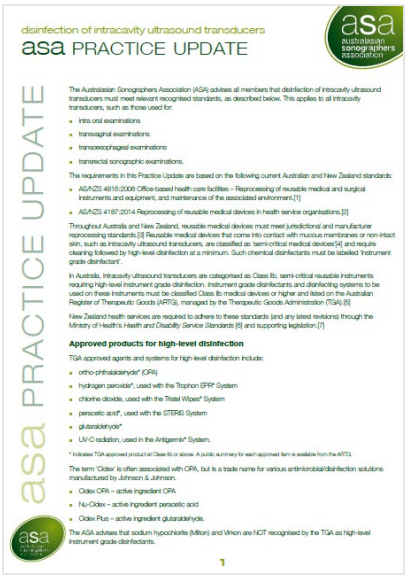
- intra oral examinations
- transvaginal examinations
- transoesophageal examinations
- transrectal sonographic examinations.

Approved products for high-level disinfection

TGA approved agents and systems for high-level disinfection include chlorine dioxide, used with the Tristel Wipes* System.

* Indicates TGA approved product at Class IIb or above. A public summary for each approved item is available from the ARTG.

The ASA advises that sodium hypochlorite (Milton) and Virkon are NOT recognised by the TGA as high-level instrument grade disinfectants.


disinfection of intracavity ultrasound transducers
asa PRACTICE UPDATE

asa PRACTICE UPDATE

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- intra oral examinations
- transvaginal examinations
- transoesophageal examinations
- transrectal sonographic examinations.

The requirements in this Practice Update are based on the following current Australian and New Zealand standards:

- AS/NZS 4815:2006 Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment.[1]
- AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organisations.[2]

Throughout Australia and New Zealand, reusable medical devices must meet jurisdictional and manufacturer reprocessing standards.[3] Reusable medical devices that come into contact with mucous membranes or non-intact skin, such as intracavity ultrasound transducers, are classified as 'semi-critical medical devices'[4] and require cleaning followed by high-level disinfection at a minimum. Such chemical disinfectants must be labelled 'instrument grade disinfectant'.

In Australia, intracavity ultrasound transducers are categorised as Class IIb, semi-critical reusable instruments requiring high-level instrument grade disinfection. Instrument grade disinfectants and disinfecting systems to be used on these instruments must be classified Class IIb medical devices or higher and listed on the Australian Register of Therapeutic Goods (ARTG), managed by the Therapeutic Goods Administration (TGA).[5]

New Zealand health services are required to adhere to these standards (and any latest revisions) through the Ministry of Health's *Health and Disability Service Standards* [6] and supporting legislation.[7]

Approved products for high-level disinfection

TGA approved agents and systems for high-level disinfection include:

- ortho-phthalaldehyde* (OPA)
- hydrogen peroxide*, used with the Trophon EPR* System
- chlorine dioxide, used with the Tristel Wipes* System
- peracetic acid*, used with the STERIS System
- glutaraldehyde*
- UV-C radiation, used in the Antigerm* System.

* Indicates TGA approved product at Class IIb or above. A public summary for each approved item is available from the ARTG.

The term 'Cidex' is often associated with OPA, but is a trade name for various antimicrobial/disinfection solutions manufactured by Johnson & Johnson.

- Cidex OPA – active ingredient OPA
- Nu-Cidex – active ingredient peracetic acid
- Cidex Plus – active ingredient glutaraldehyde.

The ASA advises that sodium hypochlorite (Milton) and Virkon are NOT recognised by the TGA as high-level instrument grade disinfectants.

1

Key Points:

- Following flexible endoscopy of the upper respiratory tract, the endoscope will need to be cleaned and decontaminated to an acceptable standard according to the Health and Technical Memorandum HTM 01-06 policy guidelines (revised March 2016). Rigid endoscopes are not covered by this document.
- It is most important to clean and remove residual mucus, blood and debris from the endoscope after use, prior to sending for decontamination. This can be effectively achieved by hand with soap and water.
- Chemical decontamination utilising wipe systems, such as chlorine dioxide, are acceptable should an Endoscopic-Washer Disinfector (EWD) be unavailable. This system should only be carried out according to a set protocol by staff fully trained in the technique.
- Every hospital or clinic should maintain a robust system of individual endoscope traceability in place and ensure that regularly audit takes place.
- It is acknowledged that endoscope contamination with prions remains a serious potential risk.
- Endoscope sheaths are not considered to provide sufficient protection in vCJD patients.

Several chemicals have good disinfection properties. These include chlorine dioxide (Tristel), hypochlorous acid / superoxidised water (Sterilox) and peracetic acid (Steris, Nu-Cidex, Persafe, Gigasept, Dopsidex).

Peracetic acid is irritant to skin and the respiratory system.

Glutaraldehyde is no longer in use as it carried high risks of inducing sensitivity.

This section is restricted to a description of chlorine dioxide since this is a popular choice of disinfecting agent in many ENT clinics throughout the UK.

Chlorine dioxide wipes (Tristel)

The chlorine dioxide system has 2 components for disinfection: impregnated wipes and foam that is generated from a can with a nozzle. The foam is added to the impregnated wipe. The system provides a rapid manual cleansing system applicable to both rigid and flexible endoscopes. A strict protocol should be followed. The endoscope is initially washed in soap and water before being wiped with the chlorine dioxide impregnated wipes. The endoscope is then rinsed in water and dried. The process takes about 2-3 minutes. Once disinfected, the endoscope should be placed in a clean plastic bag or covered lined transport tray that is appropriately labelled.

Activity of chlorine dioxide

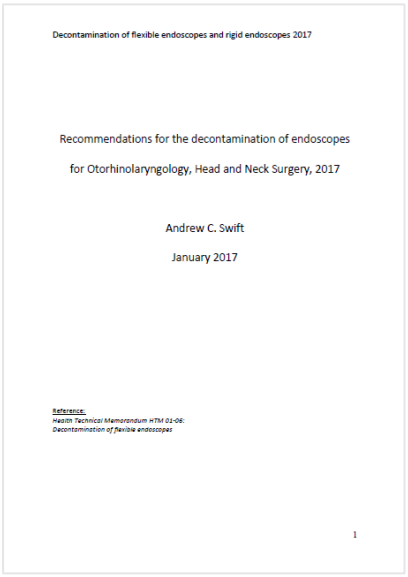
The chlorine dioxide system is active against vegetative bacteria, mycobacteria, fungi, viruses and spores. Chlorine dioxide has been shown to be effective against *Mycobacterium terrae* to demonstrate tuberculocidal activity. Chlorine dioxide has specifically been shown to be active against hepatitis C virus and HIV after 30 seconds of contact time. The chlorine dioxide wipe system is approved by market leaders who manufacture rigid endoscopes.

Advantages

- The system is simple, quick and effective and offers a traceability system
- Endoscopes can be decontaminated within the department
- The system is relatively inexpensive
- Debris can be removed from the endoscope whilst it is still moist
- Staff can be easily trained in how to use the system and the protocol is easy to follow
- The risks to hospital staff are remote

Disadvantages

- Clinical support staff will need to be fully trained and conversant with this technique
- The system requires manual cleansing of the endoscope and this is perceived as introducing an additional risk factor
- The decontamination process is often performed by the clinic staff and this could impinge on clinic support



Decontamination of flexible endoscopes and rigid endoscopes 2017

Recommendations for the decontamination of endoscopes

for Otorhinolaryngology, Head and Neck Surgery, 2017

Andrew C. Swift

January 2017

Reference:
Health Technical Memorandum HTM 01-06:
Decontamination of flexible endoscopes

1

Guidelines for Reprocessing Nonlumened Heat-Sensitive Ear/Nose/Throat Endoscopes

Laryngoscope, 122:1708–1718, 2012

Endoscopes have become an indispensable instrument in the daily activity of the ear/nose/throat (ENT) department, but their use has introduced potential health risks such as the transmission of infection. Over the years, scientific knowledge has been consolidated regarding the most appropriate ways for the correct disinfection, and numerous guidelines have been issued for both digestive and respiratory endoscopes, whereas to date specific references to ENT endoscopes do not exist.

The diagnostic ENT endoscope does not generally have an operative channel; it is shorter and thinner and has a much more frequent usage, also in the outpatient setting. As a consequence, the guidelines for digestive or respiratory endoscopes are not always functional for the ENT department in that they do not take into account the dynamics or the intensity of the work performed therein. This article proposes: 1) to standardize the correct way to carry out the disinfection procedure of heatsensitive nonlumened ENT endoscopes to reduce to a minimum the possibility of errors or oversights; and 2) to guarantee the disinfection within a limited time frame, appropriate for an ENT outpatient department. In the initial phase, the critical areas encountered in ENT endoscopy are determined. This is followed by an examination of the literature to identify existing guidelines for the reprocessing of endoscopes (mainly digestive and respiratory), with a view to establishing a common disinfection procedure for nonlumened ENT endoscopes. Finally, the new methods of disinfection developed specifically for the reprocessing of ENT endoscopes are examined and discussed.

Key Words: Heat-sensitive ENT endoscopes, cleaning, disinfection.

Many studies[2–4] agree that in nearly all of the infections transmitted to the patient after an endoscopic examination, a defect in the cleaning and disinfection procedure was shown to exist. This can occur in particular during the prewashing step (12%), the washing/disinfection step (exposure time, inappropriate disinfectant; 73%), and drying and storage (12%). Flexible endoscopes are heat sensitive and therefore cannot be sterilized in an autoclave but must be disinfected.[5]

Emerging Systems [at the time of writing, 2012]

Manual disinfection system with wipes. The disinfection system by means of wipes is a comprehensive manual sporicidal disinfection treatment of semicritical, nonchanneled, and heat-sensitive medical devices. Treatment time is only 2 to 3 minutes.

The active ingredient used in this high-level disinfection process is chlorine dioxide (ClO_2), patented under the name Tristel.

The Tristel wipe system calls for not only one wipe to be used in the high-level disinfection process, but also a wipe for the predisinfection cleaning step and one for the postdisinfection rinsing step.

The mechanical wiping action increases the efficacy of the cleaning and disinfection steps.

The wipes are for single use and thus permit tracking of the decontamination procedure to monitor its correct execution.

The use of wipes with ClO_2 leads to a notable reduction in disinfection times compared with other disinfectants of equal efficacy used in immersion methods.

The Tristel wipe system in fact was designed for the needs of the ENT department, ensuring the disinfection at the sporicidal level in time frames that permit a rapid turnaround of the instrument. In addition, they are safe from a health standpoint, because the wipes are nontoxic, nonirritating, and nonsensitizing.

The safe use of ClO2 enables a manual wiping technique not possible with the other traditional high-level disinfectants. Each wipes procedure is single use, which allows an audit trail to be implemented, because every disinfection treatment can be linked to the patient's name.

The system, even if simple to use, is manual and thus can lead to different treatment results from one operator to another. Precise and continuous training is necessary to ensure that all operators responsible for carrying out the disinfection treatment are capable of optimal performance.

A study[22] conducted at an ENT outpatient facility in an Italian hospital compared the wipe system with a traditional immersion system on a sample of 120 cases. The results demonstrated the superiority of the wipe system in lowering the microbial load, particularly with regard to biofilm-producing micro-organisms and bacteria.

The Laryngoscope
© 2012 The American Laryngological, Rhinological and Otological Society, Inc.

Contemporary Review

Guidelines for Reprocessing Nonlumened Heat-Sensitive Ear/Nose/Throat Endoscopes

Matteo Cavaliere, MD; Maurizio Iemma, MD

Laryngoscope, 122:1708–1710, 2012

INTRODUCTION

Laryngoscope 122: August 2012 Cavaliere and Iemma: Reprocessing Heat-Sensitive ENT Endoscopes
1708

Infection prevention and control in ultrasound – best practice recommendations from the European Society of Radiology Ultrasound Working Group

Insights Imaging (2017) 8:523–535

Objectives: The objective of these recommendations is to highlight the importance of infection prevention and control in ultrasound (US), including diagnostic and interventional settings.

Methods: Review of available publications and discussion within a multidisciplinary group consistent of radiologists and microbiologists, in consultation with European patient and industry representatives.

Recommendations: Good basic hygiene standards are essential. All US equipment must be approved prior to first use, including hand held devices. Any equipment in direct patient contact must be cleaned and disinfected prior to first use and after every examination. Regular deep cleaning of the entire US machine and environment should be undertaken. Faulty transducers should not be used. As outlined in presented flowcharts, low level disinfection is sufficient for standard US on intact skin. For all other minor and major interventional procedures as well as all endocavity US, high level disinfection is mandatory. Dedicated transducer covers must be used when transducers are in contact with mucous membranes or body fluids and sterile gel should be used inside and outside covers.

Conclusions: Good standards of basic hygiene and thorough decontamination of all US equipment as well as appropriate use of US gel and transducer covers are essential to keep patients safe.

Main messages: Transducers must be cleaned/disinfected before first use and after every examination. Low level disinfection is sufficient for standard US on intact skin. High level disinfection is mandatory for endo-cavity US and all interventions. Dedicated transducer covers must be used for endo-cavity US and all interventions. Sterile gel should be used for all endo-cavity US and all interventions.

Keywords Ultrasound - Infection prevention and control - Disinfection - Patient safety - Guidelines.

High level disinfection must be performed for all semicritical and critical US procedures as persistent contamination following LLD has been demonstrated, even with transducer cover use [48–51]. Agents/methods used must be in compliance with manufacturers' recommendations. One of the following may be chosen:

- Approved manual multistep disinfectant wipes (validated for HLD)
- Standardised automated validated systems (hydrogen peroxide, ultraviolet light)
- Other approved procedures that have been validated for HLD including immersion bath

Infection prevention and control in ultrasound - best practice recommendations from the European Society of Radiology Ultrasound Working Group

A randomised, single-blind comparison of high-level disinfectants for flexible nasendoscopes
The Journal of Laryngology & Otology, 1 of 7.

Objectives: To compare the microbiological efficacy, turnaround time, cost, convenience, and patient and user tolerance of Tristel Trio Wipes, PeraSafe solution and Cidex OPA solution for the high-level disinfection of flexible nasendoscopes.

Methods: Flexible nasendoscopes were used in routine clinical encounters. They were then disinfected with one of the three disinfectant methods. Surveillance cultures were taken before and after each disinfection process. Data relating to each of the study parameters were recorded.

Results: Positive bacterial cultures were discovered on nasendoscopes disinfected with PeraSafe and Cidex OPA. Tristel Trio Wipes have no capital outlay cost, the lowest running cost, the greatest convenience and the fastest turnaround time. PeraSafe had a faster turnaround time than Cidex OPA, and lower running costs.

Conclusion: Tristel Trio Wipes are equal to PeraSafe and Cidex OPA in terms of microbiological efficacy. Turnaround time and cost are dramatically reduced when using Tristel Trio Wipes compared to the other disinfectant methods.
Key words: Endoscopes; Decontamination; Otolaryngology; Laryngology

Evaluation of disinfection of flexible nasendoscopes using Tristel wipes: a prospective single blind study

Ann R Coll Surg Engl 2012; 94:185–188.

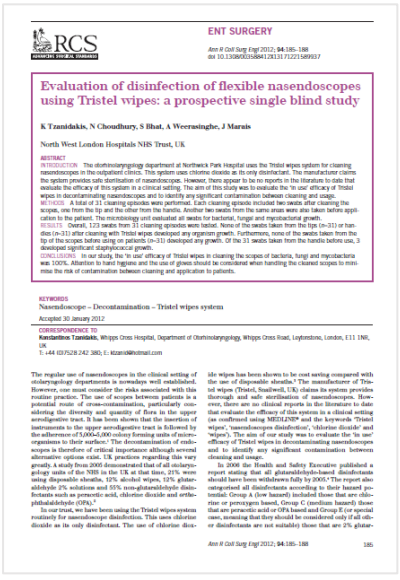
The otorhinolaryngology department at Northwick Park Hospital uses the Tristel wipes system for cleaning nasendoscopes in the outpatient clinics. This system uses chlorine dioxide as its only disinfectant. The manufacturer claims the system provides safe sterilisation of nasendoscopes. However, there appear to be no reports in the literature to date that evaluate the efficacy of this system in a clinical setting. The aim of this study was to evaluate the 'in use' efficacy of Tristel wipes in decontaminating nasendoscopes and to identify any significant contamination between cleaning and usage.

METHODS: A total of 31 cleaning episodes were performed. Each cleaning episode included two swabs after cleaning the scopes, one from the tip and the other from the handle. Another two swabs from the same areas were also taken before application to the patient. The microbiology unit evaluated all swabs for bacterial, fungal and mycobacterial growth.

RESULTS: Overall, 123 swabs from 31 cleaning episodes were tested. None of the swabs taken from the tips (n=31) or handles (n=31) after cleaning with Tristel wipes developed any organism growth. Furthermore, none of the swabs taken from the tip of the scopes before using on patients (n=31) developed any growth. Of the 31 swabs taken from the handle before use, 3 developed significant staphylococcal growth.

CONCLUSIONS: In our study, the 'in use' efficacy of Tristel wipes in cleaning the scopes of bacteria, fungi and mycobacteria was 100%. Attention to hand hygiene and the use of gloves should be considered when handling the cleaned scopes to minimise the risk of contamination between cleaning and application to patients.

KEYWORDS: Nasendoscope – Decontamination – Tristel wipes system.



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ENT SURGERY

Ann R Coll Surg Engl 2012; 94:185–188
doi 10.1308/003588412X13171221589937

Evaluation of disinfection of flexible nasendoscopes using Tristel wipes: a prospective single blind study

K Tzanidakis, N Choudhury, S Bhat, A Weerasinghe, J Maruis

North West London Hospitals NHS Trust, UK

ABSTRACT

INTRODUCTION The otorhinolaryngology department at Northwick Park Hospital uses the Tristel wipes system for cleaning nasendoscopes in the outpatient clinics. This system uses chlorine dioxide as its only disinfectant. The manufacturer claims the system provides safe sterilisation of nasendoscopes. However, there appear to be no reports in the literature to date that evaluate the efficacy of this system in a clinical setting. The aim of this study was to evaluate the 'in use' efficacy of Tristel wipes in decontaminating nasendoscopes and to identify any significant contamination between cleaning and usage.

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KEYWORDS
Nasendoscope – Decontamination – Tristel wipes system

Accepted 30 January 2012

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The regular use of nasendoscopes in the clinical setting of otolaryngology departments is nowadays well established. However, one must consider the risks associated with this routine practice. The use of scopes between patients is a potential route of cross-contamination, particularly considering the diversity and quantity of flora in the upper aerodigestive tract. It has been shown that the insertion of instruments to the upper aerodigestive tract is followed by the adherence of 5,000–7,000 colony forming units of microorganisms to their surface.[1] The decontamination of endoscopes is therefore of critical importance although several alternative options exist. UK practices regarding this vary greatly. A study from 2005 demonstrated that of all otolaryngology units of the NHS in the UK at that time, 21% were using disposable sheaths, 12% alcohol wipes, 12% glutaraldehyde 2% solutions and 55% non-glutaraldehyde disinfectants such as peracetic acid, chlorine dioxide and orthophthalaldehyde (OPA).[2]

In our trust, we have been using the Tristel wipes system routinely for nasendoscope disinfection. This uses chlorine dioxide as its only disinfectant. The use of chlorine dioxide wipes has been shown to be cost saving compared with the use of disposable sheaths.[3] The manufacturer of Tristel wipes (Tristel, Snailwell, UK) claims its system provides thorough and safe sterilisation of nasendoscopes. However, there are no clinical reports in the literature to date that evaluate the efficacy of this system in a clinical setting (as confirmed using MEDLINE® and the keywords 'Tristel wipes', 'nasendoscopes disinfection', 'chlorine dioxide' and 'wipes'). The aim of our study was to evaluate the 'in use' efficacy of Tristel wipes in decontaminating nasendoscopes and to identify any significant contamination between cleaning and usage.

In 2006 the Health and Safety Executive published a report stating that all glutaraldehyde-based disinfectants should have been withdrawn fully by 2005.[4] The report also categorised all disinfectants according to their hazard potential: Group A (low hazard) included those that are chlorine or peroxygen based, Group C (medium hazard) those that are peracetic acid or OPA based and Group E (or special case, meaning that they should be considered only if all other disinfectants are not suitable) those that are 2% glutar-

Ann R Coll Surg Engl 2012; 94:185–188 185

Flexible nasoendoscopy decontamination: a comparison between Rapicide and Tristel wipes, a prospective cohort study

Gan YJ et al. Int J Otorhinolaryngol Head Neck Surg. 2018 Jan;4(1):18-23

Background: The current disinfection of nasoendoscopes in our clinic setting is a 3-step process involving Rapicide, a peracetic acid based disinfectant. Our study aimed to validate the efficacy of Tristel wipes, a chlorine dioxide based disinfectant, as a comparable alternative.

Methods: We recruited a hundred volunteers undergoing routine flexible nasoendoscopic examinations in a general ENT. We used two separate endoscopes for each examination, following which a microbiological swab was sent from the tip of each nasoendoscope. The two nasoendoscopes were then subjected to a similar 3-step decontamination process except for the second step, where they were disinfected either tristel wipes or rapicide disinfectant. After decontamination, we took a second swab from the tip of each nasoendoscope.

Results: Out of 200 swabs from the tip of the nasoendoscopes prior to decontamination, there were 82 positive cultures for the Rapicide cohort and 76 positive cultures for the Tristel wipes cohort. Regarding the post decontamination results, there were four positive swab cultures for those disinfected with Tristel wipes and one positive swab culture for the Rapicide cohort. These were analyzed by the Z score and there was no statistical difference between either the pre-decontamination swabs or the post decontaminations swabs with the p-values at p=0.298 and p=0.174 respectively. The efficacy of decontamination for the Rapicide solution was 98.8% compared to 94.7% for the Tristel wipes with p=0.147.

Conclusions: This study validates the efficacy of Tristel wipes as a comparable alternative to peracetic acid based disinfectants for disinfection of flexible nasoendoscopes.

Keywords: Nasoendoscope, Decontamination, Tristel wipes, Peracetic acid, Rapicide.

A recent study in the UK validated the 'in use' efficacy of tristel wipes system in 2012, a chlorine dioxide based disinfectant, in the cleaning of flexible nasoendoscopes in preventing bacterial transmission in a clinic setting.[6] The tristel wipes system is a 3-part system that kills all organisms on a pre-cleaned surface in 30 seconds.[7] It is known to be easy to use and more economic than endoscope sheaths.[6] The health and safety executive of the NHS illustrated that Tristel wipes is the safer disinfectant, Class A (low hazard), when compared to Rapicide PA.[5] Additionally as a portable system, it is useful in an inpatient setting without access to disinfecting facilities. The current study aimed to evaluate the efficacy of tristel wipes as a comparable alternative to peracetic acid based disinfectants.

Tristel wipes does have a few important advantages. Firstly, being a portable system, it can be brought to the emergency department or to the wards. This is important as even though most of ENT patients are outpatients, those that are inpatients often may be carriers of MRSA, vancomycin-resistant Enterococci (VRE) or even tuberculosis. Secondly, it takes about 2 to 3 minutes for decontamination with Tristel compared to the 15-minute turnaround time that Rapicide requires.[7] This difference is significant given the fast turnaround time we have in the ENT setting and the number of naeoendoscopes we have in our inventory given its costs is usually a limiting factor.

This study validates the efficacy of Tristel wipes as a comparable alternative to peracetic acid based disinfectants for disinfection of flexible nasoendoscopes. Tristel wipes being a more portable and faster system compared to high-level disinfectants, does provide us with a more convenient and ergonomic alternative. Furthermore, this study suggests that to bring down the cost of the Tristel trio wipe system, it is possible to use only the sporicidal (chlorine dioxide based) wipe coupled with a multizyme solution and sterile water. We would also like to highlight there is a need to be meticulous in each step of disinfection of the nasoendoscopes regardless of the type of disinfection used.

International Journal of Otorhinolaryngology and Head and Neck Surgery
Gan YJ et al. Int J Otorhinolaryngol Head Neck Surg. 2018 Jan;4(1):18-23
http://www.ijorl.com
pISSN 2454-5929 | eISSN 2454-5937

DOI: http://dx.doi.org/10.18203/issn.2454-5929.ijohns20175607

Original Research Article

Flexible nasoendoscopy decontamination: a comparison between Rapicide and Tristel wipes, a prospective cohort study

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Received: 09 May 2017
Revised: 01 October 2017
Accepted: 03 October 2017

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ABSTRACT

Background: The current disinfection of nasoendoscopes in our clinic setting is a 3-step process involving Rapicide, a peracetic acid based disinfectant. Our study aimed to validate the efficacy of Tristel wipes, a chlorine dioxide based disinfectant, as a comparable alternative.
Methods: We recruited a hundred volunteers undergoing routine flexible nasoendoscopic examinations in a general ENT. We used two separate endoscopes for each examination, following which a microbiological swab was sent from the tip of each nasoendoscope. The two nasoendoscopes were then subjected to a similar 3-step decontamination process except for the second step, where they were disinfected either tristel wipes or rapicide disinfectant. After decontamination, we took a second swab from the tip of each nasoendoscope.
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Conclusions: This study validates the efficacy of Tristel wipes as a comparable alternative to peracetic acid based disinfectants for disinfection of flexible nasoendoscopes.

Keywords: Nasoendoscope, Decontamination, Tristel wipes, Peracetic acid, Rapicide

INTRODUCTION

The regular use of flexible nasoendoscopes in Otolaryngology departments is well established. They are routinely used in both the inpatient and outpatient setting to examine the upper aero digestive tract. Flexible nasoendoscopes are expensive, heat sensitive and delicate instruments. They are significantly different from other endoscopes as they are shorter, thinner and do not have an internal channel. Reprocessing is required to prepare the scope for reuse in the next patient. Inadequate decontamination may lead to cross-contamination and iatrogenic infection in subsequent patients.[1] Many disinfectant guidelines have been written to address the respiratory and digestive tracts but far fewer have been written for the disinfection of flexible nasoendoscopes.

The Spaulding classification classifies medical equipment based on the risk of infection depending on their usage.[2] They can be divided into critical, semi-critical or non-critical devices. Given that flexible nasoendoscopes have contact with intact mucosal membrane surfaces, they are

GUIDELINES FOR CLEANING TRANSVAGINAL ULTRASOUND TRANSDUCERS BETWEEN PATIENTS

Ultrasound in Med. & Biol., Vol. -, No. -, pp. 1–4, 2017.

The purpose of this article is to provide guidance regarding the cleaning and disinfection of transvaginal ultrasound probes. These recommendations are also applicable to transrectal probes.

Key Words: Infection control, Ultrasound, Transducer cleaning.

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Technical Note

GUIDELINES FOR CLEANING TRANSVAGINAL ULTRASOUND TRANSDUCERS BETWEEN PATIENTS

INTRODUCTION

CLASSIFICATION OF MEDICAL DEVICES ACCORDING TO INFECTION RISK

Transvaginal ultrasound probe contamination by the human papillomavirus in the emergency department

Emergency Medicine Journal - 2012

Objective:
To determine if human papillomavirus (HPV) DNA can be detected on the transvaginal sonography (TVS) probe in the emergency department (ED) and whether the current barrier method plus disinfection can prevent HPV contamination of the TVS probe.

Methods:
This was a two-part cross-sectional study. In the first part, surveillance samples were taken from the TVS probe for HPV DNA detection daily for 2 months. In the second part, patients presenting with early pregnancy complications were identified in the ED and high vaginal swabs were taken for HPV DNA testing. Several probe swabs were taken to identify if contamination was possible in cases where the procedure was done on an HPV carrier.

Results:
A total of 120 surveillance samples were obtained, nine of which (7.5%) tested positive for HPV DNA. In the second part, 76 women were recruited, of whom 14 (18.4%) were HPV carriers. After the procedure and disinfection of the probe, three out of the 14 probe samples (21%) were HPV DNA positive.

Conclusions:
HPV is commonly encountered in the ED and contamination of the TVS probe with HPV is possible. Although it is difficult to prove the viability and infectivity of the virus, vigilant infection control measures should be maintained.

High level disinfection reduces HPV contamination of transvaginal sonography probes in the emergency department

Emergency Medicine Journal - 2012

Our previous study reported in your journal in 2012 found that 7.5% of the transvaginal sonography (TVS) probe samples were human papillomavirus (HPV) DNA positive in our Emergency Department, when a barrier was applied along with low level disinfection using a quaternary ammonia based agent. [1]

M'Zali et al also demonstrated that TVS probes remained substantially contaminated by HPV, C. trachomatis, mycoplasmas, Gram-positive and Gram- negative bacteria with low level disinfection. [2]

According to the Centres for Disease Control and Prevention (CDC) guidelines, transvaginal probes, as they have direct contact with mucosal membranes, should be processed using a high level disinfection method. [3] However, many suitable agents can potentially damage the transducer and reduce its life span.

Since the discovery of substantial HPV contamination in 2011, our department has adopted high level disinfection techniques using the Tristel TRIO wipes system [Tristel Solutions Ltd, U.K.], which is a chlorine dioxide based agent specially designed for endocavity ultrasound probes as well as certain endoscopes.

After implementation of the new disinfection method for 1 year, we performed another surveillance sampling of the TVS probe. A total of 50 samples were collected daily over 50 consecutive days between March and May 2013. All samples were HPV DNA negative by PCR performed as previously described. [1]

Our latest results provide encouraging evidence that barrier methods together with high level disinfection can successfully reduce HPV contamination of the TVS probe. The associated increase in cost is worthwhile to ensure a low risk of contamination.

Reference: 1. Ma ST, Yeung AC, Chan PK, Graham CA. Transvaginal ultrasound probe contamination by the human papillomavirus in the emergency department. Emerg Med J. 2013 Jun;30(6):472-5.
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3. http://www.cdc.gov/hicpac/pdf/guidelines/disinfection_nov_2008.pdf

Transvaginal ultrasound probe contamination by the human papillomavirus in the emergency department

Shuk Ting Christine Ma,[1] A C Yeung,[2] Paul Kay Sheung Chan,[2] Colin A Graham[1]

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Emergency Medicine Journal

High level disinfection reduces HPV contamination of transvaginal sonography probes in the emergency department

POTENTIAL INFECTION CONTROL RISKS ASSOCIATED WITH ULTRASOUND EQUIPMENT – A BACTERIAL PERSPECTIVE

Ultrasound in Med. & Biol., Vol. -, No. -, pp. 1–6, 2016

Ultrasound equipment used in trans-abdominal (TA) and trans-vaginal (TV) examination may carry bacterial contamination and pose risks to infection control during ultrasound examination. We aimed to describe the prevalence of bacterial contamination on ultrasound probes, gel, machine keyboard and cords and examined the effectiveness of low- and high-level disinfection techniques. This study was performed at a public hospital and a private practice. A total of 171 swabs were analyzed and bacterial species were identified using matrix-assisted laser desorption/ionization time-of-flight (MALDI-TOF) analysis and polymerase chain reaction (PCR). Sixty percent of TA probes and 14% of TV probes had evidence of bacterial contamination after an ultrasound examination. Low-level disinfection was partially effective, but 4% of probes were still contaminated by spore-forming species. Some heated gel samples were highly contaminated with the environmental bacterium Brevundimonas aurantiaca, suggesting the gel was conducive to bacterial growth. Ultrasound machines, probe cords and gels were identified as potential sources of bacterial contamination and need to be cleaned and changed regularly to minimize risks of infection.

We have shown that significant proportions of both TA and TV probes have bacterial contamination at the end of a procedure and that this can include potential pathogens. Although LLD measures were generally effective, a low (,5%) rate of bacterial contamination remained. HLD effectively removed all remaining contaminants from the probe. Infection control processes for ultrasound focus on the probe, but we have also shown that probe cords and machine keyboards present significant sources of infection and that this can include potential pathogens. This is consistent with other studies highlighting the importance of cleaning ultrasound equipment, which can be a potential vector in the transmission of infectious agents (Keys et al. 2015; M'Zali et al. 2014).


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Original Contribution

POTENTIAL INFECTION CONTROL RISKS ASSOCIATED WITH ULTRASOUND EQUIPMENT – A BACTERIAL PERSPECTIVE

INTRODUCTION

Guidelines for Transoesophageal Echocardiography Probe Cleaning and Disinfection from the British Society of Echocardiography

British Society of Echocardiography (BSE) – 2011.

The clinical utility of Transoesphageal Echocardiography (TOE) is well established. Being a semi-invasive procedure however, the potential for transmission of infection between sequential patients exists. This has implications for the protection of both patients and medical staff. Guidelines for disinfection during gastrointestinal endoscopy (GIE) have been in place for many years1,2. Unfortunately, similar guidance is lacking with respect to TOE. Although traversing the same body cavities and sharing many similarities with upper GIE, there are fundamental structural and procedural differences with TOE which merit special consideration in establishing a decontamination protocol. This document provides recommendations for TOE probe decontamination based on the available evidence, expert opinion and modification of current British Society of Gastroenterology guidelines.

The basic principles underpinning successful decontamination of reusable equipment are cleaning and either manual or automated disinfection. TOE probes do not warrant sterilisation, as they are endoscopes not penetrating sterile areas of the body (unlike laparoscopes or other surgical instruments), nor is sterilisation a feasible option.

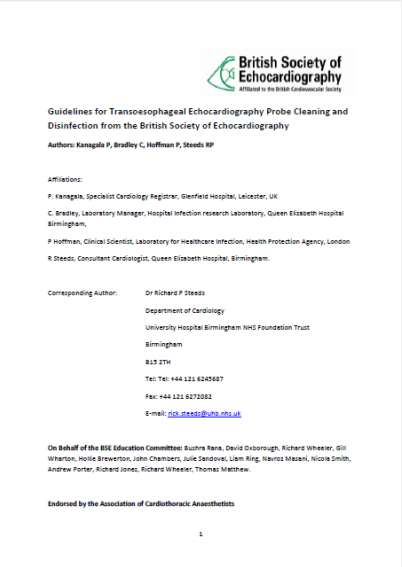
Choice of disinfectant. A wide range of products exist (see Table 2), but the choice of disinfectant should be governed by microbicidal range, safety and compatibility with the TOE probe[1,11]. Agents used to date include aldehydes, hydrogen peroxide, peracetic acid, chlorine dioxide, superoxidised water and alcohols. The use of alcohols and aldehydes as a disinfectant is discouraged owing to their fixative properties, resulting in protein (including prion protein) retention on the probe1.

Manual Disinfection. Methods include the use of disinfectant wipes and baths. If manual disinfection is to be performed, particular care must be taken to ensure that disinfection is carried out not only to the probe tip and shaft but also to the handle, cable and sections of the socket. It is important to ensure strict adherence to the manufacturer's instructions. Steps to be taken:

- Remove a wipe from closed sachet;
- Unfold the wipe and lay out on the palm the operator's hand;
- Cover the wipe with disinfectant solution to the volume recommended by the manufacturer, ensuring there is no delay between dispensing and use
- Wipe the whole TOE surface until it has been covered with disinfectant;
- All areas of the surface must come into contact with the wipe at least once for the recommended contact time;
- Discard the wipe to clinical waste.

Rinse thoroughly after disinfection to remove disinfectant residues after processing.

Record keeping. Each probe should have a unique identifier and a record of the probe used on each patient and the decontamination procedure should be retained in the patient records and/or the unit records.



British Society of Echocardiography

Guidelines for Transoesophageal Echocardiography Probe Cleaning and Disinfection from the British Society of Echocardiography

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Endorsed by the Association of Cardiothoracic Anaesthetists

1

Guidance for the decontamination of intracavity medical devices: the report of a working group of the Healthcare Infection Society

Bradley CR, et al., Guidance for the decontamination of intracavity medical devices: the report of a working group of the Healthcare Infection Society, Journal of Hospital Infection (2018), https://doi.org/10.1016/j.jhin.2018.08.003

Background: Intracavity medical devices (ICMDs) are used in a wide variety of healthcare settings. The approach to their decontamination and the resources available also differ widely. Their potential for infection transmission is considerable.

Aim: To produce a comprehensive risk assessment-based approach to the decontamination of ICMDs, accompanied by an adaptable audit tool.

Key recommendations:

- All ICMDs should be classified according to the risks of infection transmission they pose.
- The processes used for their decontamination should conform to a basic essential quality requirement, with progression towards a higher quality best practice.
- After each use, all probes should initially be thoroughly cleaned.
- Those probes with mucous membrane contact should be disinfected in a controlled process.
- Manual disinfection would comply with essential quality requirements; validated automated disinfection would constitute best practice.
- Areas of the probe and its associated parts that make contact with an operator's contaminated hand also require decontamination.
- Probes in contact with sterile body tissue should be sterilized; use of sterile barriers alone is unacceptable.
- All those who decontaminate ICMDs should be trained to do so.
- Decontamination should occur in facilities adequately equipped and allowing a defined dirty to clean flow pathway.
- There should be a documentation system that allows tracking and tracing of each probe to the patients it is used on and each episode of its decontamination.
- That a healthcare provider can supply adequate decontamination should be established before a new ICMD is acquired.
- The process of ICMD decontamination should be regularly audited.

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Journal of Hospital Infection xxx (2018) 1–10

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevier.com/locate/jhin

Guidelines

Guidance for the decontamination of intracavity medical devices: the report of a working group of the Healthcare Infection Society

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ARTICLE INFO

Article history:
Received 1 June 2018
Accepted 1 August 2018
Available online xxx

Keywords:
Intracavity medical device
Probe
Disinfection
Decontamination

SUMMARY

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https://doi.org/10.1016/j.jhin.2018.08.003
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Please cite this article in press as: Bradley CR, et al., Guidance for the decontamination of intracavity medical devices: the report of a working group of the Healthcare Infection Society, Journal of Hospital Infection (2018), https://doi.org/10.1016/j.jhin.2018.08.003

A new technique for the sterilisation of the ultrasound transducer used in egg retrieval procedures in IVF

Meridis E, Talmor A, Turner C, Lavery S & Trew G
Affiliations - IVF Unit, Hammersmith Hospital, London, UK.

Introduction: The egg collection procedure plays a key role in every In Vitro Fertilization cycle. The laparoscopic method originally developed by Steptoe and Edwards in the 1970's for aspirating oocytes from graafian follicles has evolved to the trans-vaginal ultrasound guided egg retrieval procedure currently used for the

majority of cases. A key element for this procedure is the ultrasound transducer which is inserted vaginally covered with a latex cover to enable accurate needle entry and precise follicle aspiration. Unlike other materials that are also necessary for the oocyte retrieval procedure, the ultrasound transducer needs a uniquely

designed technique for cleaning and sterilisation between cases.

Methods: The traditional technique that involves bathing the ultrasound transducer in an antiseptic solution for a certain amount of time has been replaced by a new technique, using recent innovations in sterilisation technology and particularly the Tristel Sporicidal Wipe (TSW) system. An observational study of the new technique for a period of one year and retrospective comparison with an historical control group has been carried out, with fertilization and pregnancy rates as primary end points, but also measuring parameters like cost effectiveness, time consumption and convenience of use.

Results and Discussion: So far, results have shown no difference in oocyte fertilization rates or pregnancy rates between the new technique and the traditional one, proving that the Tristel Sporicidal Wipe (TSW) system is efficacious and safe for use in an IVF setting. The new technique has also been found to be faster, easier to use and more cost effective than the traditional one.

An IVF laboratory should always use materials, supplies and methodology that maintain the prospective developmental potential of each oocyte. The Tristel Sporicidal Wipe (TSW) system seems to be a superior alternative to the traditional technique for ultrasound transducer sterilisation in transvaginal oocyte collection procedures.

BFS SUMMER COLLEGE 2006 - POSTER PROGRAMME

Assisted Conception

P1
A new technique for the sterilisation of the ultrasound transducer used in egg retrieval procedures in IVF

Meridis E, Talmor A, Turner C, Lavery S & Trew G

Affiliations - IVF Unit, Hammersmith Hospital, London, UK.

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Methods: The traditional technique that involves bathing the ultrasound transducer in an antiseptic solution for a certain amount of time has been replaced by a new sterilisation technique, using recent innovations in sterilisation technology and particularly the Tristel Sterilising Wipe (TSW) system. An observational study of the new technique for a period of one year and retrospective comparison with an historical control group has been carried out, with fertilization and pregnancy rates as primary end points, but also measuring parameters like cost effectiveness, time consumption and convenience of use.

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An IVF laboratory should always use materials, supplies and methodology that maintain the prospective developmental potential of each oocyte. The Tristel Sterilising Wipe (TSW) system seems to be a superior alternative to the traditional technique for ultrasound transducer sterilisation in transvaginal oocyte collection procedures.

P2
The place of clomifene for ovulation induction in an era of high-tech assisted reproduction

Bekhit MT, Greenwood JM, & Currie D

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Introduction: The clinical use of medical induction of ovulation is becoming increasingly questioned in the current era of assisted conception. This study aims to assess the effectiveness and outcome of clomifene therapy as a first line of treatment for couples with anovulatory (WHO II) and unexplained infertility at our subfertility clinic.

Methods: Eighty couples planned for clomifene therapy were included in this study. Analysis included age, parity, menstrual pattern, duration of infertility, BMI, PCO status, dose of clomifene, number of treatment cycles and treatment outcome.

Results and Discussion: Total number of women treated was 76 (4 never started treatment for social reasons). Pregnancy rate was 70%. For women using 50 mg of clomifene, compared with 38% for those using 100 mg. Pregnancy rate was also higher in nulliparous women, those who had oligomenorrhea, and low BMI. No cases of ovarian hyperstimulation occurred. Clinical pregnancy rate was 49% (37/76). Nine women had early miscarriage (24%) and one had an ectopic pregnancy. Live birth rate was 36% (27/76), one had a singleton live birth after having an ectopic pregnancy and 2 women had twins (7%), both were dichorionic. One set of twins was delivered at 34 weeks by CS for IUGR with hypospadias in one baby, while the other set of twins were delivered by CS at 36 weeks. Cost of treatment (clomifene only) per baby was £40. Proper selection of couples for relatively simple, less invasive and less expensive treatment with adherence to good practice guidelines achieves pregnancies in a more 'natural' way and reduces stress, complications for women and the overall cost to the NHS.

Analysis of the integrity of ultrasound probe covers used for transvaginal examinations

2019 Australasian College for Infection Prevention and Control

Background: Ultrasound probe covers should be used for any ultrasound procedure where there is contact with body fluids or mucous membranes. The type and quality of probe covers used in clinical practice differ widely and studies in the early 1990s showed that condoms were more superior for use with transvaginal examinations than commercial probe covers. Since then, although products have changed, there have been no further studies to assess the breakage rate of different probe covers. The objectives of this study were to assess the integrity of the most commonly used probe covers for transvaginal ultrasound examinations under clinical conditions and report the breakage rate.

Methods: The study was conducted in public and private hospitals and private practices. A total of 500 covers for each of 10 brands of commercial covers and condoms (latex and latex free) were distributed to ultrasound practitioners. The transvaginal ultrasound examination practice was unchanged except that all covers were placed in a container for assessment instead of discarding post ultrasound examination. All covers were collected and subjected to a water leak test. Covers that broke upon deployment onto the ultrasound probe prior to the ultrasound examination were recorded. All covers that were broken or had microtears or leaks were recorded as well as photographed. Statistical analysis was performed along with Chi-squared analysis of the data and significance considered at $P < 0.05$.

Results: None of the commercial covers broke upon deployment onto the ultrasound probe prior to ultrasound examination. A total of 5000 probe covers were examined post-transvaginal ultrasound examinations. The breakage rate for condoms ranged from 0.4% to 13% and for commercial covers 0-5%. Statistical analysis of the data by comparison of p-values revealed that the best performing group were the commercial non-latex probe covers and worst performing group were the non-latex condoms.

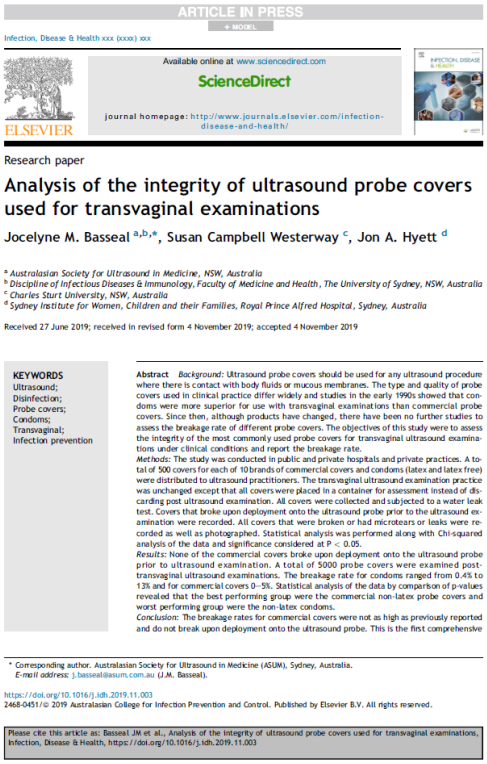
Conclusion: The breakage rates for commercial covers were not as high as previously reported and do not break upon deployment onto the ultrasound probe. This is the first comprehensive study that thoroughly evaluated the integrity of commercial covers and condoms used for transvaginal ultrasound examination in a clinical setting, with regards to brand, numbers and types of covers assessed.

Hence, we reaffirm that high level disinfection must be used after every ultrasound examination where a transvaginal probe comes in contact with mucous membranes or body fluids.

Highlights

- Previous studies (over 2 decades old) reported that condoms were superior to commercial probe covers for transvaginal ultrasound.
- This study assessed 5000 covers (a mix of latex and latex free) post transvaginal ultrasound using a water leak test.
- Best performing group were the commercial non-latex covers and breakage rates were not as high as previously reported.
- None of the 2500 commercial covers broke upon deployment on the ultrasound probe.
- Strengths included high sample size (500 of each brand), variability of brands, multi-site study & different users (sonographers and sonologists).

KEYWORDS
Ultrasound; Disinfection; Probe covers; Condoms; Transvaginal; Infection prevention



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Research paper

Analysis of the integrity of ultrasound probe covers used for transvaginal examinations

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Received 27 June 2019; received in revised form 4 November 2019; accepted 4 November 2019

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Disinfection;
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Condoms;
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Abstract *Background:* Ultrasound probe covers should be used for any ultrasound procedure where there is contact with body fluids or mucous membranes. The type and quality of probe covers used in clinical practice differ widely and studies in the early 1990s showed that condoms were more superior for use with transvaginal examinations than commercial probe covers. Since then, although products have changed, there have been no further studies to assess the breakage rate of different probe covers. The objectives of this study were to assess the integrity of the most commonly used probe covers for transvaginal ultrasound examinations under clinical conditions and report the breakage rate.
Methods: The study was conducted in public and private hospitals and private practices. A total of 500 covers for each of 10 brands of commercial covers and condoms (latex and latex free) were distributed to ultrasound practitioners. The transvaginal ultrasound examination practice was unchanged except that all covers were placed in a container for assessment instead of discarding post ultrasound examination. All covers were collected and subjected to a water leak test. Covers that broke upon deployment onto the ultrasound probe prior to the ultrasound examination were recorded. All covers that were broken or had microtears or leaks were recorded as well as photographed. Statistical analysis was performed along with Chi-squared analysis of the data and significance considered at $P < 0.05$.
Results: None of the commercial covers broke upon deployment onto the ultrasound probe prior to ultrasound examination. A total of 5000 probe covers were examined post-transvaginal ultrasound examinations. The breakage rate for condoms ranged from 0.4% to 13% and for commercial covers 0–5%. Statistical analysis of the data by comparison of p-values revealed that the best performing group were the commercial non-latex probe covers and worst performing group were the non-latex condoms.
Conclusion: The breakage rates for commercial covers were not as high as previously reported and do not break upon deployment onto the ultrasound probe. This is the first comprehensive

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https://doi.org/10.1016/j.idh.2019.11.003

Please cite this article as: Basseal JM et al., Analysis of the integrity of ultrasound probe covers used for transvaginal examinations, Infection, Disease & Health, https://doi.org/10.1016/j.idh.2019.11.003

Modern endoscopic-based exploration of the female reproductive tract: a model for developing countries?

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The paper by Campo and Molinas (2008) is an overview of the challenges faced in the field of infertility and the importance of having a suitable investigation technique that can improve IVF treatments whilst overcoming the challenges faced. The paper eludes to transvaginal endoscopic procedures being the possible answer to these problems which include cost and need for a specialist to carry out the procedures. The author outlines that to be able to suggest the systemic use of transvaginal endoscopic procedures the system must have high levels of accuracy and low complication rates.

An overview is provided of the materials and instruments that need to be in place to carry out these procedures. This highlights the method of disinfection of these instruments. The paper specifies that the disinfectant should be *"non-toxic (i.e. aldehyde free), biodegradable, effective against all kinds of microorganisms, inclusive resistant spores, cheap, easy to use, instrument friendly."* The paper recommends Tristel Trio Wipes System, due to its short contact time and effectiveness against many microorganisms of concern and even the most resistant spores. This highlights the easy usage of Tristel Trio Wipes System and how it is highly efficacious against the contamination that these devices could face.

This comprehensive model then discusses the viability of the use of transvaginal endoscope procedures. This includes the techniques, accuracy, and patient compliance among other relevant parameters.

Human Reproduction 2008 doi:10.1093/humrep/den162

Modern endoscopic-based exploration of the female reproductive tract: a model for developing countries?

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Introduction

Infertility has been notorious for its time-consuming and prolonged explorations and the resultant delay in diagnosis. This delayed diagnosis adds to the burden of the patient and, in spite of the higher pregnancy rate and lower cost reported with traditional treatment algorithm as first-line therapy compared with liberal referral to assisted reproduction technologies (ART) (Karande *et al.*, 1999), has stimulated physicians and specialized centres to promote the latest approach. This strategy has the additional problem, especially for developing countries, that ART carry a higher risk of neonatal and maternal morbidity than natural conception, even in the absence of multiple pregnancy (Helmerhorst *et al.*, 2004; Ombelet *et al.*, 2005, 2006).

Recent observations demonstrate that exploration of the female reproductive tract is not only useful for diagnosis and treatment but also necessary for enhancing the *in vitro* fertilization—embryo transfer (IVF-ET) results. Indeed, a Cochrane review including three RCT shows that laparoscopic salpingectomy prior to IVF-ET in patients with hydrosalpinges improves pregnancy, ongoing pregnancy and live birth rates (Johnson *et al.*, 2002). Furthermore, the incremental cost of the surgical intervention to achieve this higher live birth rate was reported to be beneficial (Strandell *et al.*, 2005).

Everybody agree on the value of an accurate exploration of the female reproductive tract for the management of infertility but opinions greatly differ as how and to which extent these investigations should be performed. In current practice hysterosalpingography (HSG) is still used as a first-line investigation, although it is not a pain-free (Tur-Kaspa *et al.*, 1998) and risk-free procedure and even when its sensitivity, specificity and prognostic values for the management of the infertility are debatable (Glatstein *et al.*, 1997; Swart *et al.*, 1995; Mol *et al.*, 1997, 1999). This option is largely based on the absence of alternatives since endoscopic procedures (e.g. conventional laparoscopy and hysteroscopy) demanding high skills and sophisticated equipments do not fulfil the criteria of being minimally invasive, affordable and accessible.

Although conventional laparoscopy is considered the gold standard for the exploration of the female reproductive tract, it is for several reasons not suitable as a first-line investigational technique. Laparoscopy is an expensive procedure requiring hospitalization, operating room and general anaesthesia, as in open abdominal surgery. The procedure is invasive and not without morbidity and mortality. Indeed, even in experienced hands the blind transabdominal access can cause major blood vessel and bowel injury (Jansen *et al.*, 1997; Brosens *et al.*, 2003), whereas the distension medium (i.e. CO2 pneumoperitoneum) causes discomfort and additional hazards (Molinas and Koninckx, 2000; Molinas *et al.*, 2001; Nguyen *et al.*, 2002; Kissler *et al.*, 2004). Furthermore, the see-and-treat possibility of laparoscopy requires the presence of a high skilled reproductive surgeon at the diagnostic screening procedure, which is not always feasible.

The exploration of the female reproductive tract should be as easy as HSG and as accurate as standard laparoscopy. No conclusive answer has been given until now, but the transvaginal ultrasound and endoscopic procedures offer probably the most efficient and accurate solution to the problem. The challenge is for both developed as developing countries identical: to find a low cost and easily accessible diagnostic procedure with operative possibilities for offering the fastest and minimal invasive lane to pregnancy.

In this article we outline a challenging concept for the management of infertility in both developed and developing countries: a model based on ambulatory endoscopic techniques (i.e. modern mini-hysteroscopy and transvaginal laparoscopy) for the exploration of the female reproductive tract, describing their diagnostic and operative possibilities and limitations.

Ambulatory endoscopic exploration of the female reproductive tract

In order to propose the systematic use of transvaginal endoscopic procedures, such as mini-hysteroscopy and transvaginal hydro-laparoscopy (TVL), and to avoid the still well-established delay in indication, it is mandatory to perform the technique in an easily accessible ambulatory environment, ideally at the same time as the transvaginal sonography (TVS). The most important challenge for this approach is to

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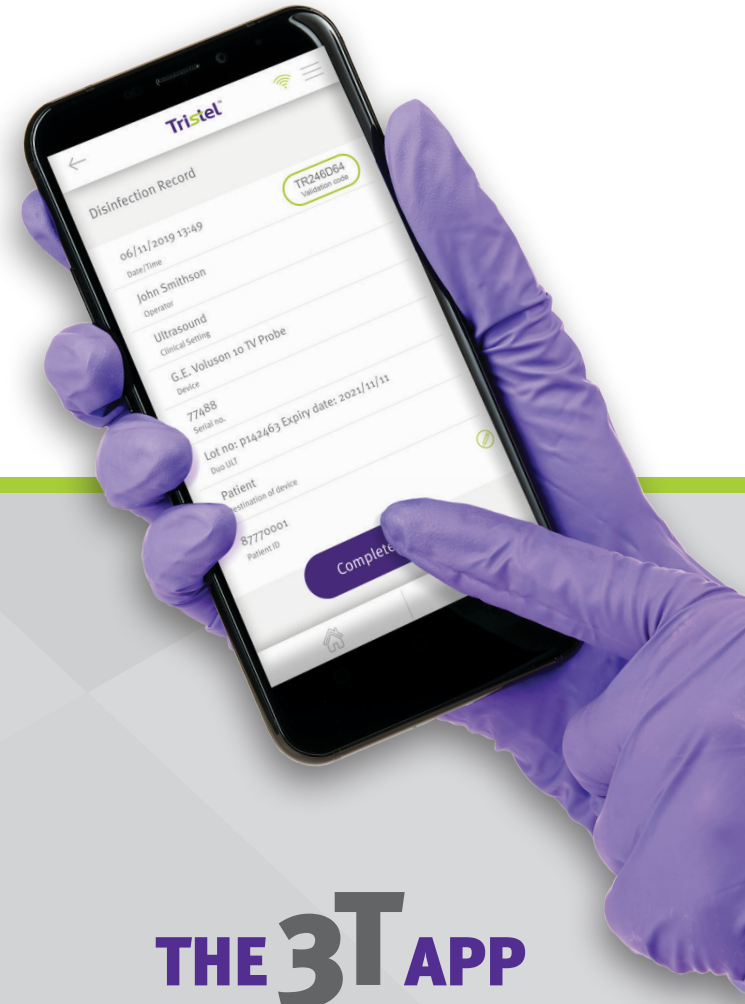

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GENERATES A 3T DISINFECTION RECORD INCLUDING DATE & TIME STAMP AND A UNIQUE VALIDATION CODE FOR EASY TRACKING AND TRACING.

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DISINFECT
YOUR DEVICE

TRACE
DISINFECTION EVENTS

REVIEW
AND REPORT ON RECORDED DATA

TAKING TRACEABILITY DIGITAL

Tristel 3T is designed to provide traceability and compliance in a smart and efficient way. It comprises a Portal for setup, data management and reporting purposes and an App to record Tristel disinfection events.

FULL PROCESS CAPTURE

When used in tandem with a Tristel product the 3T App captures operator, disinfectant (LOT and Expiry) and instrument data, as well as a patient reference if required. Disinfectant data can be inputted manually, or by scanning the 2D matrix barcodes on Tristel packaging.

OPTIONAL TRAINING

Short videos within the 3T App guide the operator through each disinfection event to ensure compliance with user instructions. If an operator is fully trained on the use of a Tristel product, then the 3T Administrator can switch the videos off for this operator simply by un-ticking the video box within the Portal. If a reminder is needed, the videos can be switched back on at the push of a button.

CUSTOMISED OPERATING PROCEDURES

Standard Operating Procedures can vary. 3T has been developed with agility in mind; if a pre-cleaning step is to be added to a Tristel Duo disinfection event, or if only the high-level disinfection step needs to be captured as part of a Trio decontamination event, then the 3T Administrator can configure the procedure as such via the Portal.

TOUCH-FREE OPERATION

When training videos are switched on, 3T App operators can move through the stages by waving at the 3T device. This avoids any contact between the operator's gloved hands and the 3T device during the disinfection event.

SECURITY & DATA PROTECTION

3T is hosted by Tristel on a Microsoft Azure Cloud server. Microsoft has taken measures to secure data and has more than 20 Cloud computing related security certificates in place, including ISO 27001 (information security) and ISO 27018 (personal data protection). Microsoft also complies with both international and industry-specific compliance standards and participates in rigorous third-party audits that verify security controls. In addition, 3T has been developed according to the latest General Data Protection Regulation (GDPR), which came into force on 25th of May 2018.

PAPERLESS OPERATION

Disinfection records produced by the 3T App are digital. Synchronisation between the App and Portal occurs when a WiFi connection is established.

Upon completion of a disinfection event, the 3T App produces a digital disinfection record with a date & time stamp and a unique Validation Code.

Each record is then uploaded to the Disinfection Log on the 3T App, and synchronised to the 3T Portal when WiFi is enabled. 3T Administrators can access all Disinfection Records via the Portal, and extract them into a CSV for simple integrability.

WHAT'S INCLUDED:

- 3T device with 3T App installed
- Access to the 3T Portal
- Setup and Update Instructions
- Charger accessories
- Service (2 years)
- Warranty (1 year)

DEVELOPED BY:

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For any enquiries, please contact your local Tristel representative or email 3TSupport@tristel.com

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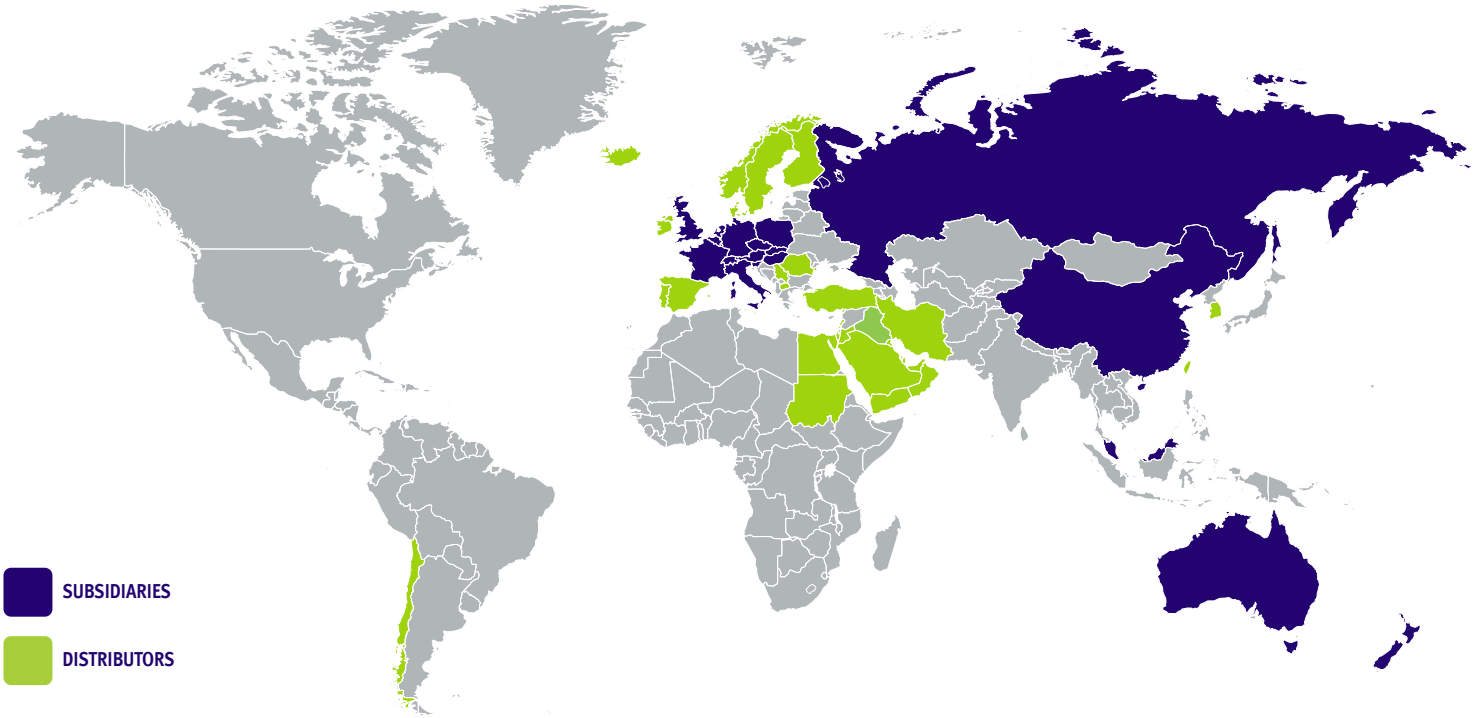

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