

History

History

Alternatives

Developments

ClO₂

ClO₂ (2)

ClO₂ (3)

Innovation

Innovation

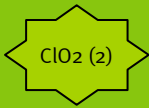
Products

Products

Instrument decontamination and chlorine dioxide

- History of instrument decontamination in UK
- Alternatives replacing Glutaraldehyde
- Chlorine dioxide: the most widely used substitute in the UK
- Innovation in instrument decontamination

Tristel



Historical developments in the UK

Flexible endoscope market

- Since 1957: 2% Glutaraldehyde
- 1990's: growing concerns over toxicity

Technical note on cleaning and disinfection (ESGE, ESGENA)	<u>Adverse effects for medical staff and environment:</u> allergies (skin, eyes, ENT), dermatitis, conjunctivities, nasal irritation, asthma, potentially cytotoxic and genotoxic <u>Adverse effects on patients:</u> colitis, diarrhea, etc.
Allergic contact dermatitis from GA in health-care workers (Contact Dermatitis, 2000:45, 150-156)	468 healthcare workers were tested per patch test for GA induced allergies; infection control nurses were 8 times more allergic than other nurses
Nurses sue over disinfectant exposure (BBC 2000)	Two healthcare workers have successfully sued their hospital employers and won very substantial compensation claims for the harm caused to them by glutaraldehyde; The largest pay-out was well in excess of £150,000

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Historical developments in the UK

Reasons for replacing glutaraldehyde (GA)

- GA's dangers to health and safety
- Increasing number of endoscopic procedures involve biopsies
→ need for a more effective and broad spectrum biocide
- Certain micro-organisms become resistant to GA
'It was discovered that *M. chelonae* could survive in glutaraldehyde and cause the false diagnosis of suspected tuberculosis patients.'
- Contamination issue (especially in machines) as aldehydes fix proteins onto surfaces and help form biofilms
- Time consumption of disinfection cycle → cost effectiveness
→ GA is no longer used in UK hospitals

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- Two movements: automation and replacement of GA
- 1995: Alternatives to GA
 - Peracetic Acid (Nu-Cidex, Steris)
 - Chlorine dioxide (Tristel)
 - Ortho-phthalaldehyde (Cidex OPA) – UK users sceptical as still aldehyde!
- Similarities of the two alternatives: PAA (CH₃-CO-O-OH) and ClO₂
 - Oxidising agents
 - Sporicidal
 - Shorter contact time
 - Safer than aldehydes (differ in degree of safety and user comfort)
 - More concern over potential damage to instruments than experienced with GA
- With time, Tristel's chlorine dioxide became user's choice, with more than 60% of all UK hospitals using a Tristel product

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Recent Developments

Adoption of track and trace

The Chief Medical Officer in Winning Ways (Working together to reduce Hospital Acquired Infection), December 2003: *“Staff will ensure that there is an audit trail for each recycled item”*

- confirm process completed properly
- Ability to identify and contact patients potentially affected by a failure

Move to single-use of disinfectant

- fears concerning variant Creutzfeldt Jacob’s disease (vCJD)
- prions cannot be destroyed by chemical disinfectants
- re-usable disinfectant solutions can become the medium for transmission of the prion from one patient to another as it survives in the disinfectant

Both developments recognised in regulatory framework

- United Kingdom (via the NHS Estates Health Technical Memoranda – HTM2030)
- European Directive for the decontamination of endoscopes EN 15883 (4)

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Chlorine dioxide

Efficacy

Spores:

Bacillus cereus
Bacillus subtilis
Bacillus subtilis var niger
Clostridium difficile

Mycobacteria:

Mycobacterium avium-intracellulare
Mycobacterium chelonae
Mycobacterium fortuitum
Mycobacterium terrae
Mycobacterium tuberculosis
Mycobacterium tuberculosis Poli-R

Viruses:

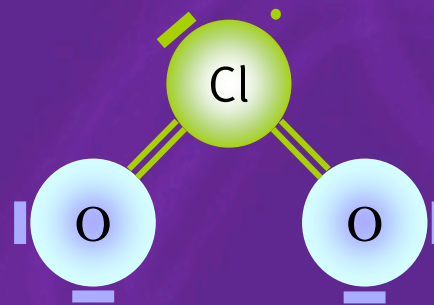
Canine parvovirus
Coxsackivirus B3
Hepatitis A
Hepatitis B
Hepatitis C
Herpes simplex virus Type 1
HIV Type 1
Human norovirus
Influenza virus Type A2
Poliovirus Type 1
Poliovirus Type 2
SARS

Fungi:

Aspergillus niger
Candida albicans

Bacteria:

Acetobacter baumannii
Clostridium difficile
Enterococcus faecium (vancomycin resistant)
Enterococcus hirae
Echerichia coli
Pseudomonas aeruginosa
Pseudomonas aeruginosa (gentamicin resistant)
Staphylococcus aureus
Staphylococcus aureus (menthicillin resistant)



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Chlorine Dioxide

Contact time

- Sporicidal in 5 minutes or even 30 seconds (depending on concentration and product format)

Health and Safety

- Non toxic
- Non-sensitising or irritant (proven for eyes, skin, and respiratory tract)
- Not carcinogenic
- Neutral ph (skin)
- Two inert components (organic acid blend and sodium chlorite solution) mix within seconds to create ClO₂ in aqueous solution
- Safe to dispose, no hazard to environment

Tristel products in various concentrations have been used in the United Kingdom since 1995 without any health and safety incident.

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Chlorine Dioxide

Compatibility with materials

- Tristel's products contain corrosion inhibitors
- Easily soluble in water (easy removal of residues on materials)
- It is an oxidising agent! – handling according to description is important to prevent cosmetic damage to instruments
- Compatibility confirmed with certain instrument manufacturers

Other use areas

- Acknowledged as disinfectant for water treatment
 - Widely used as disinfectant in food industry
 - Replaced chlorine in paper and pulp industry
- Chlorine dioxide has been widely used for decades
- Tristel's ClO₂ has a pedigree of 10 years in the medical field

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Innovation in Products

Uniqueness and adaptability

- Tristel is the only chlorine dioxide product formulated for medical applications
- Only sporicidal chemistry designed to meet the many specific needs within the modern hospital → range of products



Tristel Skin
product
(2007)

Ease and precision

- Generated at time and point of use → precise control
- One product, one concentration, one strength → no confusion

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Innovation (2)

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Innovation in Products

Single-use

- Ensures highest and most consistent effectiveness with every use
- No need for test kits and less human error
- Preventing CJD: research has yet to show ways to destroy prions; effective way to help prevent cross contamination – use solution once

Traceability

- Validation and control of sterilisation routine
- Audit book as quality management system
- Ensures compliance with highest standards → peace of mind for the hospital and its patients
- Practical, easy to use

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Tristel products in Belgium

Instruments

Tristel Fusion

- burstable sachet to produce 5l chemical sterilant
- sporicidal in 5 minutes
- not affected by water quality
- minimal packaging and storage space
- controlled dose leading to accurate and constant concentration of the working solution
- de-skilled process, ease and comfort of use
- achieving single-use without greater cost of disinfectant



In summary, Tristel Fusion, is a rapid action sporicide that is proven safe for users and can be employed as a single-use disinfectant.

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Tristel products in Belgium

Tristel Sterilising Wipe as part of the Tristel Wipes System

- Wipe activated with a foam
- Sporicidal in 30 seconds
- Trace labels on each wipe sachet
- Complemented by pre-clean wipes and rinse wipes
- Provides complete sterilisation cycle without need of water
- Audit book to provide traceability and QMS



Surfaces

Tristel DUO

- Foam to boost biocidal performance of low or intermediate disinfectant wipes
- Sporicidal in 30 seconds
- Only sporicidal high-level disinfectant for surfaces



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Thank you for your attention!

Feel free to ask questions now.

Tristel products are distributed in Benelux by

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