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EFFECTIVE SOLUTION IN STERILIZING SENSITIVE SURGICAL INSTRUMENTS

BUSINESS DEVELOPMENT MANAGER LOW TEMPERATURE SOLUTIONS - APAC JONSON JI

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- Aldehyde vs Oxidative.
- Methods of Sterilization.
- Low temperature sterilization & disinfection.
- Spaulding's classification.
- Levels of disinfection requirements for different equipment.

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Aldehyde vs Oxidative



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How does an aldehyde work?

- The most common/cheap HLD chemistry we know is in the form an aldehyde
 - Activated alkaline glutaraldehyde (GTA) "CIDEX"
 - Ortho-phthalaldehyde (OPA) "CIDEX OPA"
- Inactivates microorganisms via cross-linking or fixation of protein

Protein fixed to lumen walls



Aldehyde resistance

 As the aldehyde group of disinfectants have been around since the 1960s, there are reports of aldehyde resistance in bacteria

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Aldehyde resistance

Infect Control Hosp Epidemiol. 2017 Jul;38(7):784-791. doi: 10.1017/ice.2017.75. Epub 2017 May 2.

Disinfectant Susceptibility Profiling of Glutaraldehyde-Resistant Nontuberculous Mycobacteria.

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Abstract

OBJECTIVE Activated alkaline glutaraldehyde (GTA) remains one of the most widely used high-level disinfectants worldwide. However, several reports have highlighted the potential for nontuberculous mycobacteria to develop high-level resistance to this product. Because aldehyde resistance may lead to cross-resistance to other biocides, we investigated the susceptibility profile of GTA-resistant Mycobacterium chelonae and M. abscessus isolates to various disinfectant chemistries. METHODS High-level disinfectants commonly used in the reprocessing of endoscopes and other heat-sensitive, semicritical medical equipment, including different formulations of aldehyde-based products and oxidizing agents, were tested against 10 slow- and fast-growing, GTA-susceptible and GTA-resistant, Mycobacterium isolates in suspension tests and carrier tests at different temperatures. RESULTS While peracetic acid- and hydrogen peroxide-based products (ie, Cidex, Aldahol, Cidex OPA) showed variable efficacy against GTA-resistant strains despite the ability of some formulations (Aldahol) to overcome the resistance of some of these isolates, especially when the temperature was increased from 20°C to 25°C. CONCLUSIONS Application permitting, oxidizing chemistries may provide a safe alternative to aldehyde-based products, particularly in GTA-resistant mycobacterial outbreaks. Infect Control Hosp Epidemiol 2017;38:784-791.

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Aldehyde resistance

Journal of Applied Microbiology 1997, 82, 519-526

Glutaraldehyde-resistant Mycobacterium chelonae from endoscope washer disinfectors

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P.A. GRIFFITHS, J.R. BABB, C.R. BRADLEY AND A.P. FRAISE. 1997. Glutaraldehyde is used to disinfect flexible and other heat-sensitive endoscopes often with the aid of automated systems. *Mycobacterium chelonae* is being isolated with increasing frequency from these washer disinfectors and processed endoscopes. This has, on occasions, led to misdiagnosis and iatrogenic infections. Recent reports suggest that disinfecting machines, on a sessional or regular basis, with 2% glutaraldehyde may have selected and therefore encouraged the growth of strains of *Myco. chelonae*, possibly in biofilm, with decreasing susceptibility to glutaraldehyde. In view of this, the resistance of three strains of *Myco. chelonae* var. *chelonae* (the type strain NCTC 946

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Aldehyde resistance



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Brief report

Aldehyde-resistant mycobacteria bacteria associated with the use of endoscope reprocessing systems

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Key Words: Disinfection Resistance Glutaraldehyde Ortho-phthaldehyde Bacteria can develop resistance to antibiotics, but little is known about their ability to increase resistance to chemical disinfectants. This study randomly sampled 3 automated endoscope reprocessors in the United States using aldehydes for endoscope disinfection. Bacterial contamination was found after disinfection in all automated endoscope reprocessors, and some mycobacteria isolates demonstrated significant resistance to glutaraldehyde and ortho-phthaldehyde disinfectants. Bacteria can survive aldehyde-based disinfection and may pose a cross-contamination risk to patients.

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Aldehyde resistance

 Porins are proteins associated with the cell wall surface that allow the transport of chemicals into and out of the cell. They are also a major protein component of the outer mycobacteria cell wall.
Glutaraldehyde and other aldehydes are surface-acting molecules that act by cross linking proteins.



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How does a oxidative work?

- A oxidative 'destroys' the microorganism by oxidizing or 'burn up' the cell membrane causing cell death
 - Hydrogen peroxide formulations 'Resert HLD'
 - Peracetic acid 'PAA'



Protein removed from walls

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Oxidizer vs Aldehyde



Methods of Sterilization





Methods of Sterilization





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Methods of Chemical Sterilization

Method	Glutaraldehyde	Formaldehyde	Ethylene Oxide	Hydrogen Peroxide	Peracetic acid
Use	Soak	Gas	Gas	Gas	Soak
Turn around time	10 hours+	4 hours+	24 hours	30mins	18mins
Sterilization	Sterile*	Sterile	Sterile	Sterile	Sterile*
Processing Volume	small	large	large	large	small
Risk to infection	high	low	low	low	low
Toxicity	carcinogen	carcinogen	carcinogen	burns	burns*
Material damage	high	med	low	low	low
Risk of residue	high	high	low	low	low

Spaulding Classification

Device Classification	Patient Contact	Examples	Inactivation Level
Non-critical	Intact skin		Cleaning, Low/Intermediate/High- Level Disinfection
Semi-critical	Mucous membranes or non-intact skin		Cleaning and Sterilization When the device cannot tolerate sterilization then HLD is acceptable
Critical	Sterile areas of the body, including blood contact		Cleaning and Sterilization

http://canadianbestpracticequalityaudits.com/wp-content/uploads/2012/11/Spauldings-Criteria.pdf

What makes a sterilizer?

An effective and validated sterilizer should have the following:

- Run and pass Biological Indicator as routine check
- ISO 14937:2009, Sterilization of healthcare products
- Validation and endorsements from OEM manufacturers

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• Extensive testing and laboratory reports/papers

V-PRO maX Low Temp H2O2 Sterilizer

- No plasma
- 28 min cycles
- Large chamber 136L
- Very easy to use, no unwanted aborts



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V-PRO maX Low Temp H2O2 Sterilizer

- Inbuilt moisture check
- No added time

Application Application (Meson Description Indication



Moisture Check

Minimize moisture related aborts



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Thank you!

