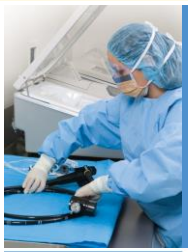
EDUCATION

STERIS UNIVERSITY



An Update on High Level Disinfection and Sterilization Options for Flexible Endoscopes

One Integrated Approach to Healthcare.

STERIS

Disclaimer

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Learning Objectives

Upon completion of this program, you will be able to:

- Review current standards and guidelines regarding flexible endoscopes
- Discuss the advantages and disadvantages of high level disinfection and sterilization methods

Definitions

- Regulations
  - A rule or directive made and maintained by an authority
  - Mandatory
- Standards
  - Provide requirements and specifications that can be used to ensure consistency and fit for purpose
  - National and International (often the same, often not)
  - Voluntary, but can become mandatory
    - Act of legislation – New Jersey adoption of standards published by Association for the Advancement of Medical Instrumentation (AAMI)
    - If you claim compliance

Definitions

- Guidelines, Recommended Practices, Technical Information reports
  - Technical guidance, information or preferred procedures regarding a given topic
    - e.g., AAMI TIRs, AORN Guidelines for Perioperative Practice
  - Voluntary but with interpretation

Agencies with Regulations and Mandatory Standards

CMS Centers for Medicare & Medicaid Services

OSHA Occupational Safety and Health Administration www.osha.gov

Americans with Disabilities Act

FDA U.S. Food and Drug Administration

Agencies that Provide Accreditation Services

CMS.gov
Centers for Medicare & Medicaid Services

ACCREDITATION ASSOCIATION for AMBULATORY HEALTH CARE, INC.

DNV

IASE The Gold Standard

The Joint Commission
HELPING HEALTH CARE ORGANIZATIONS HELP PATIENTS

Ohio Department of Health

AOA AMERICAN OSTEOPATHIC ASSOCIATION

High-Level Disinfection (HLD) and Sterilization BoosterPak

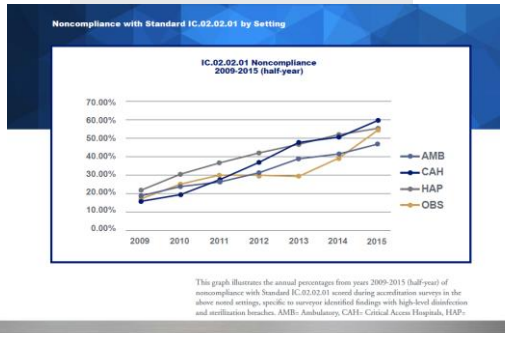
The Joint Commission

LEADERSHIP
RISK ASSESSMENT
STERILIZATION
ENVIRONMENT OF CARE
HIGH-LEVEL DISINFECTION
HR – COMPETENCY AND TRAINING
APPENDIX – STANDARDS

Primary Standard Governing HLD and/or Sterilization Processes for All Settings:

Standard IC.02.02.01: Reducing the risk of infections associated with medical equipment, devices, and supplies

EP2: Performing intermediate, high-level disinfection and sterilization of medical equipment, devices, and supplies



This graph illustrates the annual percentages from years 2009-2015 (half-year) of noncompliance with Standard IC.02.02.01 scored during accreditation surveys in the above noted settings, specific to surveyor identified findings with high-level disinfection and sterilization breaches. AMB= Ambulatory, CAH= Critical Access Hospitals, HAP=

Groups That Provide Standards and Guidelines

AAMI
APIC
AORN
SCNA
CDC SAFER · HEALTHIER · PEOPLE
IAHCSMM Instrumental to Patient Care 2015 CORPORATE PARTNER
ASGE
SHEA The Society for Healthcare Epidemiology of America
NFPA National Fire Protection Association The authority on fire, electrical, and building safety

Association for the Advancement of Medical Instrumentation

User Standards

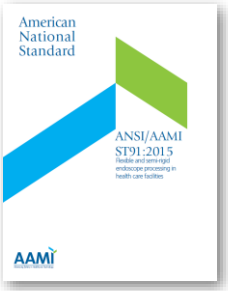
AAMI

- **ANSI/AAMI ST 91, 2015**: Flexible and semi-rigid endoscope processing in health care facilities
- **ANSI/AAMI ST 58, 2013**: Chemical sterilization and high-level disinfection in healthcare facilities. 3rd edition
- **AAMI/ANSI ST 41, 2008**: Ethylene oxide sterilization in healthcare facilities, safety and effectiveness
- **AAMI TIR 34: 2014:** Water for reprocessing of medical devices

What is ANSI/AAMI ST58?

Guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers for use in hospitals and other health care facilities

What is ANSI/AAMI ST 91?



Flexible and semi-rigid endoscope reprocessing in health care facilities

AAMI TIR34 (2014), Endoscopy Water

- Utility water: Rinsing following cleaning
- Critical water: Rinsing following disinfection
  - Some systems provide extensively treated water
- Control of any water storage or distribution systems is essential
- Biofilm development and cross-contamination

Type of Water		Utility Water[1]		Critical Water
Water Use		Flushing/Washing/Rinsing		Final Rinse[2]/Steam
Specifications:				
	Units			
Hardness	mg/L	< 150[3]		< 1
Conductivity (mg/L = ppm)	µS/cm	< 500		< 10
pH[4]		6 – 9		5 – 7
Chlorides	mg/L	< 250		< 1
Bacteria	cfu/mL	n/a	<10[5]	< 10
Endotoxin	EU/mL	n/a	<20[5]	< 10

Guidelines

- CDC Guideline for Decontamination and Sterilization in Healthcare Facilities (2008)
- ASGE/SHEA/SGNA/APIC: Multi-society guideline on reprocessing flexible gastrointestinal endoscopes (2011)
- SGNA: Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes (2016)
- SGNA: Guideline for Use of High Level Disinfectants & Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes (2015)
- AORN Guideline for Cleaning and Processing Flexible Endoscopes and Endoscope Accessories (2015)

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 17, 2015

This document supersedes: "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance" (available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf) issued April 1996.

The draft of this document was issued on May 2, 2011.

Increased Focus on Reprocessing Validations

- Quality of Reprocessing Instructions
- Attention to Human Factors
- Cleaning Validations

"IT IS IMPORTANT TO NOTE THAT CLEANING, DISINFECTION AND STERILIZATION ARE DISTINCTLY DIFFERENT PROCESSES"* FDA

* Reprocessing Medical Devices in Healthcare Settings: Validation Methods & Labeling, March 2015, Pg.6

New FDA Guidance on Reprocessing (March 17, 2015)

B. Semi-Critical Devices

Semi-critical devices are devices that contact intact mucous membranes or non-intact skin. They do not ordinarily penetrate tissues or otherwise enter normally sterile areas of the body. Intact mucosal surfaces are relatively resistant to small numbers of spores. However, these devices should be reprocessed to be free from all microorganisms. Users should be instructed to thoroughly clean these devices and then reprocess them by sterilization. If the device design does not permit sterilization (e.g., device materials cannot withstand sterilization), then high level disinfection should be used.

Examples of semi-critical devices include duodenoscopes, endotracheal tubes, bronchoscopes, laryngoscope blades and other respiratory equipment, esophageal manometry probes, diaphragm fitting rings, and gastrointestinal endoscopes.

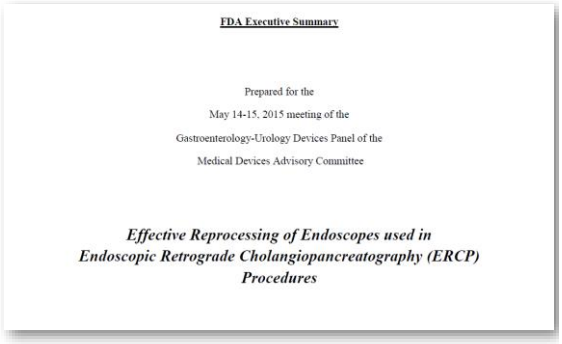
Heat-stable devices (e.g., rigid endoscopes) should be processed by steam sterilization. For heat-labile devices, available "low temperature" reprocessing

[2] Spaulding, EH. The role of chemical disinfection in the prevention of nosocomial infections. In: Brachman PS, Eickoff TC, eds. Proceedings of the International Conference on Nosocomial Infections, 1970. Chicago: American Hospital Association, 1971: 254-274

10

Spaulding Classification

Patient Contact	Examples	Device Classification	Minimum Inactivation Level
Intact skin		Non-Critical	Cleaning and/or Low/Intermediate Level Disinfection
Mucous membranes or non-intact skin		Semi-Critical	Cleaning and Sterilization (or High Level Disinfection)
Sterile areas of the body, including blood contact		Critical	Cleaning and Sterilization



FDA Executive Summary

Prepared for the
May 14-15, 2015 meeting of the
Gastroenterology-Urology Devices Panel of the
Medical Devices Advisory Committee

Effective Reprocessing of Endoscopes used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures

FDA Panel, May 2015

- Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee
  - duodenoscopes should be redesigned
  - devices should be reclassified as critical
  - contact with blood or normally sterile tissue

*"To date, only liquid chemical sterilants have been cleared by FDA specifically for sterilization of complex endoscopes, such as duodenoscopes. Ethylene oxide sterilizers have general claims and do not have specific claims for sterilization of duodenoscopes." **

*FDA Executive Summary: Effective Reprocessing of Endoscopes used in Endoscopic Retrograde Cholangiopancreatography Procedures, pg. 40

CDC HEALTH ADVISORY, 9/11/2015

- Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices
- Provide training to all personnel who reprocess devices
- Regularly monitor and document adherence to cleaning, disinfection, sterilization, and device storage procedures
- Provide feedback from audits to personnel regarding their adherence
- Allow adequate time for reprocessing
- Maintain documentation of reprocessing activities
- Protocols ensure that healthcare personnel can readily identify devices that have been properly reprocessed
- Follow manufacturer IFUs for maintenance and repair of devices

Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, 9/17/2015:

- Sub-set of devices
- Greater likelihood of microbial transmission
- Represent a high risk of infection if they are not adequately reprocessed
- Persistent device contamination despite following IFUs
- Failure to meticulously follow manufacturer instructions for reprocessing
- Continued use of devices despite integrity, maintenance and mechanical issues

Infections and Outbreaks

Centers for Disease Control

- "Endoscopes most commonly linked to health care-associated outbreaks and pseudo-outbreaks"
- Flexible endoscopes represent high-risk devices
  - High levels of bacterial contamination
    - Mouth - 200+ species
    - Large intestine - 1,000 species
- Complex designs
- Numerous reports of breaches in reprocessing

January 15, 2016
Senate Committee: Scope Outbreak Worse Than Reported

Industry silence, hospital missteps, porous regulation cited

- The global wave of "superbug" infections linked to contaminated duodenoscopes was much wider than previously believed and could have been largely avoided, Senate investigators have concluded.
- Between 2012 and 2015, at least 250 people in 25 outbreaks worldwide were sickened by the tainted instruments
- The FDA, in turn, failed to alert hospitals, health care workers and the public for 17 months after learning of the potential hazard

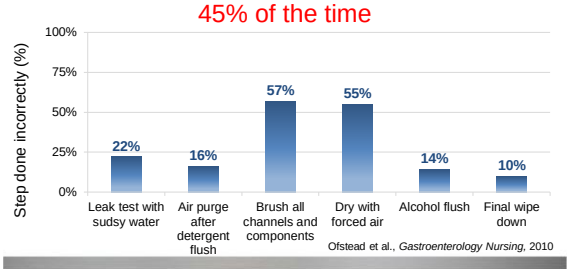
by Adam Marcus (Gastro and Endoscopy News)

What Technology Hazards are Lurking in your Hospital?

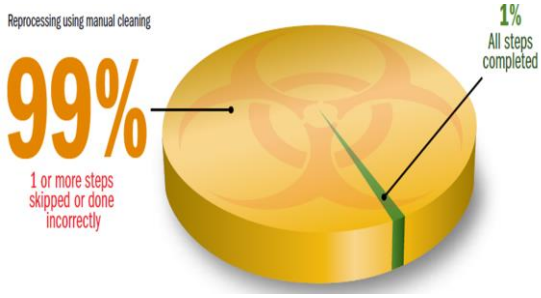
1. **Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens**
2. Missed Alarms Can Have Fatal Consequences
3. Failure to Effectively Monitor Post-operative Patients for Opioid-Induced Respiratory Depression Can Lead to Brain Injury or Death
4. Insufficient Training of Clinicians on Operating Room Technologies Puts Patients at Increased Risk of Harm
5. Unsafe Injection Practices Expose Patients to Infectious Agents

CLEANR Study: Documented non adherence with several essential steps (n = 69)

Multiple manual cleaning steps skipped 45% of the time



Ofstead et al., *Gastroenterology Nursing*, 2010



Manual cleaning n = 69; p = 0.001

Ofstead et al., *Gastroenterology Nursing*, 2010


American Journal of Infection Control

Major article

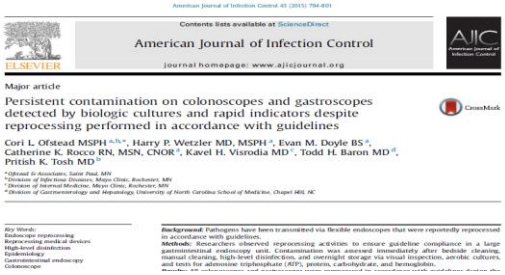
Reported gastrointestinal endoscope reprocessing lapses: The tip of the iceberg

Current risks are outdated and inaccurate (Ofstead et al, 2013; Dirlam-Langlay et al, 2013)

- Most outbreaks not published
- Most outbreaks not investigated
- Difficult to link to contaminated endoscopes
- Reviews of reprocessing practices show widespread lapses in essential steps
- Risks are greater than just infections (e.g., toxicity with aldehydes)

Nosocomial Infections via GI Endoscopes

- Infections traced to deficient practices
- Inadequate cleaning (clean all channels)
- Inappropriate/ineffective disinfection
- Failure to follow recommended disinfection practices (tap water rinse)
- Flaws and complexity in design of endoscopes or AERs
- Improper use of reprocessing equipment
- Improper drying/storage



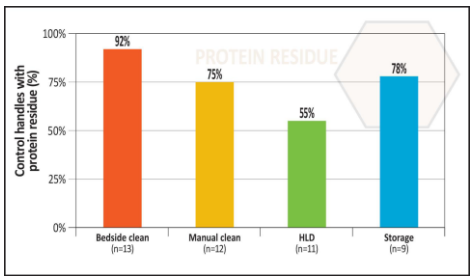
American Journal of Infection Control

Major article

Persistent contamination on colonoscopes and gastroscopes detected by biologic cultures and rapid indicators despite reprocessing performed in accordance with guidelines

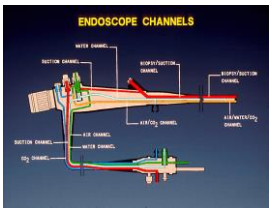
- No visible debris noted
- Viable microbes and biologic debris persist

Protein Was Never Removed During Reprocessing

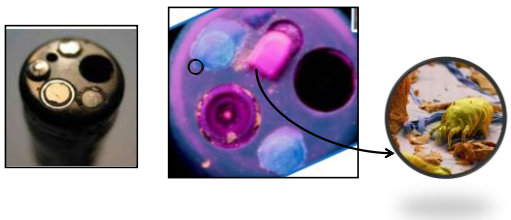


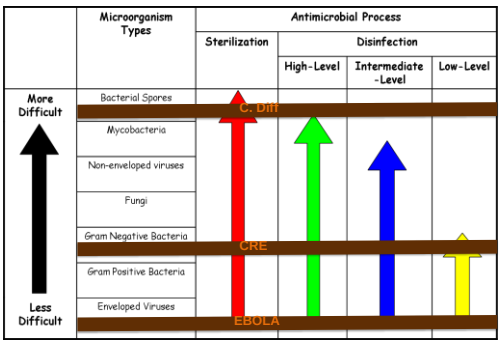
Ofstead, et al. AJIC, August 2015

Features Predispose to Disinfection Failures



- Complex Design
- Heat labile
- Long, narrow lumens
- Right angle bends
- Rough or pitted surfaces
- Springs and valves
- Damaged channels
- Heavily contaminated with pathogens, $10^{7\text{-}10}$
- Cleaning (4-6 $\log_{10}$ reduction) and HLD (4-6 $\log_{10}$ reduction) essential for patient safe instrument



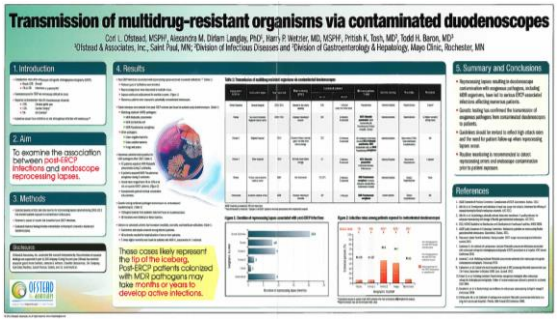


C-Diff Hits the News

- $5 billion/year in healthcare costs
- Hospital costs >40% per case
- It's all about 100% spore kill!

In 2015, It's About ERCP Scopes!

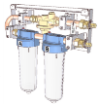
Recent Transmissions



Manual Automated

Automation

- FDA clearance
- Review claims and instructions for use
- Automate and standardize processing steps
- Reduced chemical exposure
- Defined flow of lumens
- Specific design-dependant
- Pre-cleaning still required
- Flow connector design
- Filtered tap water
- Correct use dependant on operators
- Routine maintenance



Definitions

High level disinfectant

- Product that is expected to kill all microbial organisms but not necessarily large numbers of bacterial spores, ***when used according to labeling***
- Often a liquid chemical sterilant (LCS) used for a shorter exposure time than that required to pass an FDA-defined spore inactivation test
- Disinfection and rinsing need to be controlled

Definitions

Liquid chemical sterilant

- Product validated to provide microbial kill adequate to obtain FDA clearance for a sterilization label claim (often at longer exposure times)

Sterilization

- Validated process used to render a product free from viable microorganisms, including bacterial spores.
- Liquid or gaseous process

Key Points with Disinfection

Label claims vary:

- Manufacturer IFUs (e.g. temperature, immersion time, 'rinse thoroughly')

Single use or multiple use

Multiple use disinfectants

- Label claims, maximum reuse life
- Topping off

All surfaces of device in contact

- Rinsing
- Correct water quality (bacteria-free; AAMI TIR34)
- Fresh water for every rinse (by immersion)
- Correct number of rinses

Device inspection prior to use

High Level Disinfectants

Aldehydes

- Glutaraldehyde
- OPA

Oxidizing agents

- Hydrogen peroxide
- Peracetic acid

Each Product is Unique

High Level Disinfectant/Sterilants

Chemicals	Sterilant	High Level Disinfection	Notes
3.4% glutaraldehyde 20.1% isopropanol	8 hours at 20ºC	10 mins at 20ºC	Requires activation 3 rinses following exposure
2% hydrogen peroxide	6 hours at 20ºC	8 mins at 20ºC	No activation 1 rinse
0.575% OPA	No claim (passes sporicidal test at 32 hours at 20ºC)	10 mins at 20ºC	No activation 3 rinses
2.4% glutaraldehyde	10 hours at 25ºC	45 mins at 25ºC	Requires activation 3 rinses following exposure
3.4% glutaraldehyde	10 hours at 25ºC	90 mins at 25ºC	Requires activation 'Thoroughly' rinse following exposure

www.fda.gov

Aldehydes

First marketed in 1963 as alkaline solutions

Endoscopes required low-temperature processing

- Limited reprocessing methods

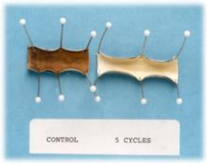
Limited inventory/quick turnover

- Decentralized reprocessing

- 1980-1990s: First reports of adverse health effects in hospitals
- Employee/patient safety concerns
  - Toxic build up
  - Fumes
  - Asthma
  - Dermatitis
  - Aldehyde induced colitis
- Closed systems

Concerns for Aldehydes

- Safety
- Protein binder
- Reduction in hospital use
  - Country-specific regulations
- Development of resistance
- Biofilms



Occupational hazards associated with endoscope high-level disinfection: Case vignettes, review of literature and recommendations for mitigation

B.H. Mobo*, L.A. Foster and M.J. Rabesa
Beth Israel Deaconess Medical Center-Harvard Medical School, Boston, MA, USA

Exposure of health workers in primary health care to glutaraldehyde

M Angel González Jara[1*], Alfonso Mora Hidalgo[1], J Carlos Avalo Gulin[1], Marcos López Albiach[2], Laura Muñoz Ortiz[3], Pere Torán Monserrat[3] and Xavier Esteva Ollé[1]

Abstract

Background: In order to avoid proliferation of microorganisms, cleaning, disinfection and sterilisation in health centres is of utmost importance hence reducing exposure of workers to biological agents and of clients that attend these health centres to potential infections. One of the most commonly-used chemical is glutaraldehyde. The effects of its exposure are well known in the hospital setting; however there is very little information available with regards to the primary health care domain.

American Journal of Infection Control xxx (2012) 1-3

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Brief report

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

Christopher W. Fisher PhD[a], Anthony Fiorello MS[a], Diana Shaffer BA[a], Mary Jackson PhD[b], Gerald E. McDonnell PhD[a,*]

[a] *Department of Research and Development, STERIS Corporation, Mentor, OH*
[b] *Mycobacteria Research Laboratories, Department of Microbiology, Immunology and Pathology, Colorado State University, Fort Collins, CO*

Emergence of Glutaraldehyde-Resistant *Pseudomonas aeruginosa*

Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants

Why the Shift to Oxidative Agents?

1 Concern: Safety

- Safe for scopes, patients, staff, environment
- Toxicity of aldehydes
- Efficacy
- Employee health
- Aldehyde resistant organisms
- Efficiency

Oxidizing Chemistries

Advantages

- Antimicrobial activity, fast cycle times
- Low risk of resistance development
- Safety profile (staff, patients, scopes)
- Low toxicity risks
- Environmentally friendly
  - Biodegradeable, no special ventilation or disposal
- Aides in removal of organic matter

Disadvantages

- Activity can vary depending on product formulation (e.g., temperature requirements)
- Variable material compatibility (product dependant)

Oxidizing Chemistries, continued

High level disinfection/sterilization:

- Formulation dependent (liquid, gas, plasma)

Reduce:

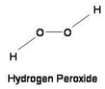
- Risk of cross-contamination
- Risk of infection with resistant bacteria

Effectiveness against:

- Biofilms
- Aldehyde resistant bacteria

Hydrogen Peroxide (H_2O_2)

- Liquid or gas
- Formulation dependent
- HLD/sterilant
  - Environmentally friendly
  - Efficacy/surface compatibility



Hydrogen Peroxide

Hydrogen Peroxide (H_2O_2), continued

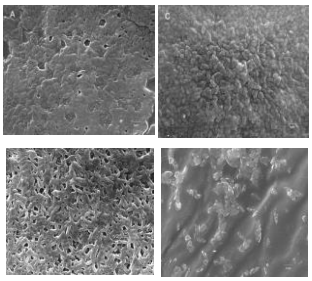
Applications

- Antisepsis
- Cleaning/Surface disinfection
- Disinfection
  - Buildings
  - Vehicles
  - Hospital rooms
  - Laboratories

Peracetic Acid (PAA)

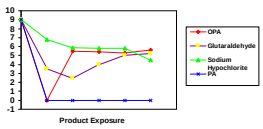
- Effective biocide
- High potency
- Effective in presence of organic soil
- No toxic residues
- Combined with proper buffers and anti-corrosives to safely disinfect / sterilize
  - Endoscopes
  - Heat sensitive devices

Biofilm Efficacy with PAA



- Efficacy against biofilms
  - Removes biofilms under worst case conditions
  - PAA minimizes biofilm development

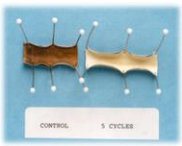
Biofilm Control

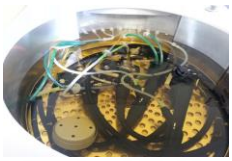


Bacterial Reduction
(log_{10} cfu/cm^2 Pseudomonas aeruginosa)

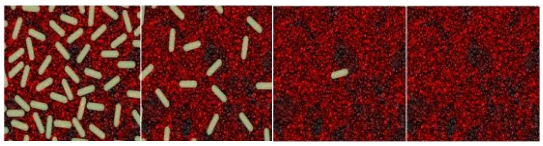
Previous Use of Aldehydes

- Aldehydes hide problems
- Leaks observed shortly after use
- Expect scope repairs





Effectiveness of Reprocessing



Contaminated | Cleaned | Disinfection | Sterilization

Sterilization Essentials

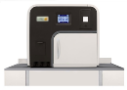
- Sterilization is dependant on adequate cleaning, rinsing and device preparation
  - Drying may also be essential
- Process claims are product specific
  - Not just the active (e.g., 'ETO')
  - Controlled processes
- Correct equipment installation, maintenance, use and periodic monitoring required for all systems
- Correct handling (including storage) required after the process

Two Sterilization Options for most Semi-Critical Flexible Endoscopes used in GI

Reprocessing Modality		
Type	**Unit**	**Notes**
Traditional Sterilization	EtO	– Uses Toxic gas. – Large Inventory Required. – 60 minute Cycle, 12 hour aeration. Known for leaving residuals. May damage devices after long term use.
Liquid Chemical Sterilization	SYSTEM 1E	– 23 minute cycle. – Less inventory needed. – Oxidative, non fixative chemistry that is safe for the user and patient. – No toxic residuals

Liquid/Gaseous Sterilization Options






Ethylene Oxide

- Ensure devices are clean and dry
  - ETO is sensitive to the presence of residual soil and water
- Low pressure (vacuum) systems
  - Venting cap required
- Sterilization parameters should be validated by endoscope manufacturer
  - Conditioning, sterilization and aeration
- Post-sterilization aeration is essential
  - Processing time typically >15 hours
- Endoscopes may have a limited number of cycles before requiring extensive repair


EPA EtO National Emission Standards

- March 2008
  - Sterilize full loads
  - Demonstrate, submit compliance status with management practice standard
  - Record keeping
    - Compliance status
    - Sterilizers not equipped with air pollution control devices
- March 2010
  - Single chamber process – no separate aerator

Recent FDA statement on EtO

Dr. William Maisel, FDA Deputy Director and Chief Scientist:

- EtO sterilization is **"not something that we routinely recommend"**
- "…There can be ethylene oxide residual levels on the products that can be harmful to patients."
- "[EtO] can damage the scopes themselves. And so we are not, at this time, recommending routine ethylene oxide sterilization."

Willman, D., *LA Times*., 2015.

Hydrogen Peroxide Gas

- Processes with and without 'plasma'
  - Vacuum processes require device venting
- Claims (lumen length and diameter restrictions) are product specific
  - Generally critical flexible endoscopes
  - Some systems include claims for single/ multiple lumened devices
  - No GI endoscope claims
- Typical sterilization time ~30 minutes
- Ensure devices are clean and dry before sterilization

Liquid Chemical Sterilization

- **One system cleared as a liquid chemical sterilant processing system cleared through the FDA**
  - Liquid chemical sterilization with peracetic acid sterilant
  - Rinsing with extensively treated water
  - Removal of bacteria, viruses, protozoa and fungi
  - Controlled rinsing (non-toxic)
- Cycle time (23 minutes)
- Validated flexible endoscope models including ERCP scopes
  - Includes specially designed connectors

"To protect the public health we must shift endoscope reprocessing from HLD to sterilization. FDA should mandate that GI endoscopes used in healthcare facilities be sterile by 2018"

Dr. Bill Rutala, 2015

GI Endoscopes: Shift from Disinfection to Sterilization

Rutala, Weber. JAMA 2014. 312:1405-1406

EDITORIAL

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Gastrointestinal Endoscopes
A Need to Shift From Disinfection to Sterilization?

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both.[1] Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.[1]

In this issue of JAMA, Epstein and colleagues[2] report findings from their investigation of a cluster of New Delhi metallo-β-lactamase (NDM)–producing *Escherichia coli* associated with gastrointestinal endoscopy that occurred from March 2013 to July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 patients

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection.[3,4] High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.[5] However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)–cleared for gastrointestinal endoscopes such as duodenoscopes.

Second, more health care–associated outbreaks and clusters of infection have been linked to contaminated endoscopes than to any other medical device.[6,7] However, until now,

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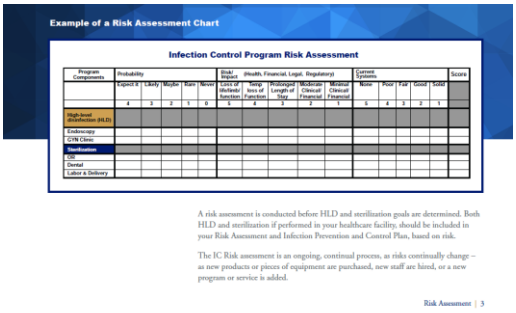
Unresolved Issue

Endoscope Shelf Life prior to reprocessing:

- AAMI ST 91: perform risk assessment
- AORN: recommends up to 5 days currently under review
- APIC: up to 7 days
- SGNA: up to 7 days
- CDC: not addressed
- FDA: not addressed
- Refer to AAMI ST91, ST58

Quality Control Plan

- Know your standards and guidelines
- Risk analysis
  - Where are your risks/hazards?
  - What have you done to reduce these?
  - Continuous improvement
- Reprocessing policy
  - Facility
  - Department
- Staff training and demonstrated competency



Conclusion

- Review current documents and standards to ensure policies and procedures are consistent with best practices
- Identify the advantages and disadvantages of aldehyde and oxidative chemistries
- Consider the benefits of sterilization versus high level disinfection when making decisions for reprocessing flexible endoscopes

Refer to scope manufacturer's instructions for proper use and handling

Action Plan

- Review current documents and standards to ensure policies and procedures are consistent with best practices
- Provide continuing education to staff based on updated information, new endoscope models, equipment and reprocessing methods
- Perform risk assessment as part of quality improvement

Questions

Useful References

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