Improving the Standard of Care for Flexible Endoscope Reprocessing
Learning Objectives

• Summarize the current evidence related to the risk of transmission of endoscopy-associated infections (EAIs).

• Discuss recommendations for Quality Control to help improve endoscope reprocessing

• Describe the methods used to monitor the efficacy of manual cleaning of flexible endoscopes

• Review current opinion of sterilization of critical flexible endoscopes
Janet Prust - Disclosure

Director – Standards and Scientific Affairs

3M Health Care Employee

Medical Solutions Division
**Why is this topic important?**

<table>
<thead>
<tr>
<th>Endoscopes are highly contaminated during procedures</th>
<th>Contaminated endoscope efficiently transmit germs</th>
<th>Infections have occurred with every type of endoscopes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcomes of endoscopy related infections are poor</td>
<td>Transmission of infection should be preventable</td>
<td>Current practices are far below standards</td>
</tr>
</tbody>
</table>

Source: See References
The Issues:

• Alarming outbreaks with duodenoscopes

• Documented pathogen transmission with other types of flexible endoscopes

• Continuing reports of persistent contamination after reprocessing

• Safety alerts, citations, reports and call to action

• New paper puts patient risk of infection as ‘common’
Flexible Endoscopes Remain Contaminated After Reprocessing – Alfa 2012

Report of contaminated endoscopes well before publicized outbreaks

Source: Alfa et.al., AJIC. 40(3). 2012
## Contamination and Outbreaks Occurring – Kovaleva 2013

<table>
<thead>
<tr>
<th>Endoscope</th>
<th>Outbreaks</th>
<th>Primary organism</th>
<th>Patient contaminated</th>
<th>Patients infected</th>
<th>Root cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper GI</td>
<td>19</td>
<td>P. aeruginosa, H. pylori, Salmonella</td>
<td>169</td>
<td>56</td>
<td>Cleaning or disinfection gaps</td>
</tr>
<tr>
<td>Sigmoidoscopy/colonoscopy</td>
<td>5</td>
<td>Salmonella, HCV</td>
<td>14</td>
<td>6</td>
<td>Cleaning or disinfection gaps</td>
</tr>
<tr>
<td>ERCP</td>
<td>23</td>
<td>P. aeruginosa</td>
<td>152</td>
<td>89</td>
<td>C/D, water bottle, contaminated AER</td>
</tr>
<tr>
<td>Bronchoscopy</td>
<td>51</td>
<td>P. aeruginosa, Mtg, Mycobacteria</td>
<td>778</td>
<td>98</td>
<td>C/D, AER, Water</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>98</strong></td>
<td></td>
<td><strong>1,113</strong></td>
<td><strong>249</strong></td>
<td></td>
</tr>
</tbody>
</table>

Report of outbreaks occurring in published literature before media reporting

High levels of Persistent Contamination on Patient Ready Endoscopes – Ofstead 2013, 2014, 2016

Ofstead and Associates Research Findings
Percent With Microbial Growth

Citation: Ofstead et al. The effectiveness of reprocessing in accordance with current guidelines. SGNA Conference Poster. 2015. APIC 2018
Additional Published Outbreaks:

1. BAJOLET O, CIOCAN D, ET AL. GASTROSCOPY-ASSOCIATED TRANSMISSION OF EXTENDED-SPECTRUM BETA-LACTAMASE-PRODUCING PSEUDOMONAS AERUGINOSA. J HOSP. INFECT 2013 (83)

2. EPSTEIN L, HUNTER J, ET AL. NEW DELHI METALLO B-LACTAMASE-PRODUCING CARBAPENEM-RESISTANT ESCHERICHIA COLI ASSOCIATED WITH EXPOSURE TO DUODENOSCOPES. JAMA 2014. (312:1447-55)

3. KOVALEVA J, DEGENER J., ET AL. METHYLOBACTERIUM AND ITS ROLE IN HEALTH CARE ASSOCIATED INFECTION. J CLIN MICROBIOL. 2014 (52). 1317-21


7. ENGLAND, ET AL. 2016. TRANSMISSION OF MDRO FROM GASTROSCOPE – 5 PATIENTS WITH CRE (9 MORE EXPOSED)

   Note: Superbug persisted through 12 reprocessing cycles

8. DIASGRANADOSE, ET AL. 2009. BRONCHOSCOPE RELATED OUTBREAK. NOTE: 19 PATIENT EXPOSED, 12 INFECTED, 2 DEATHS
## Additional Published and Reported Evidence of Contamination:

Saliou, et al. 2016. **Persistent Contamination on Endoscopes – Micro surveillance post processing with 8 day incubation;** 34% exceeded target of <25 CFU of indicator organism

<table>
<thead>
<tr>
<th>US Location</th>
<th>Facility types</th>
<th>Errors in reprocessing</th>
<th>Patients impacted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorado</td>
<td>Medical center</td>
<td>Improper cleaning</td>
<td>71</td>
</tr>
<tr>
<td>Minnesota 1</td>
<td>ASC; Outpatient clinic; 5 hospitals</td>
<td>7 incidents reported: improper cleaning/HLD; reprocessing single use device; inadequate training</td>
<td>6 – 2000 per incident</td>
</tr>
<tr>
<td>North Carolina</td>
<td>Hospital</td>
<td>No cleaning/sterilization of one channel</td>
<td>10</td>
</tr>
<tr>
<td>New Jersey</td>
<td>ASCs</td>
<td>Improper reprocessing; unchanged water/cleaning solution</td>
<td>Not reported</td>
</tr>
<tr>
<td>Ontario, Canada</td>
<td>Clinic</td>
<td>Multiple cleaning/HLD breaches</td>
<td>6800</td>
</tr>
<tr>
<td>Louisiana</td>
<td>Medical center</td>
<td>Wrong HLD temperature</td>
<td>360</td>
</tr>
<tr>
<td>British Columbia, Canada</td>
<td>Hospital</td>
<td>Bioburden allowed to dry before cleaning</td>
<td>536</td>
</tr>
<tr>
<td>California</td>
<td>Hospital; surgery center</td>
<td>Improper HLD; expired disinfectant</td>
<td>3400</td>
</tr>
<tr>
<td>Minnesota 2</td>
<td>Medical center</td>
<td>No HLD of one channel</td>
<td>2600</td>
</tr>
<tr>
<td>Florida</td>
<td>Hospital; cancer center</td>
<td>Improper cleaning of elevator channel</td>
<td>191</td>
</tr>
<tr>
<td>Georgia</td>
<td>Surgery center</td>
<td>Wrong HLD time</td>
<td>1300</td>
</tr>
</tbody>
</table>

Sources: US FDA Maude data
First reports of US duodenoscope CRE related outbreaks

- 2013 outbreaks with multi-drug resistant organisms seen

- US CDC published alert January 2014

US government action related to outbreaks occurring in published literature before media reporting
FDA seeking expert scientific and clinical opinion. 19 member advisory panel.

“Duodenoscopes and AERs do not provide a reasonable assurance safety and effectiveness”

“Manual Cleaning is a critical component.” There is a need for “…development and validation of cleaning verification assays”

“Majority of the panel suggested to reclassify duodenoscopes from semi-critical to critical and … move to sterilization.”
FDA analysis identified two recurrent themes:

- Failure to follow manufacturer instructions for reprocessing

- Continued use of devices with integrity, maintenance and mechanical issues.”

**FDA Recommendation:** “Implement a comprehensive reprocessing quality control program .. to include written procedures for monitoring, training and adherence to the program, documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure.”
Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients, Jan.13, 2016

United States Senate Health, Education, Labor and Pensions Committee
Patty Murray, Ranking Member

FROM 2012 AND MID- 2015, CLOSED-CHANNEL DUODENOSCOPES WERE LINKED TO AT LEAST 25 DIFFERENT INCIDENTS OF ANTIBIOTIC- RESISTANT INFECTIONS THAT SICKENED AT LEAST 250 PATIENTS WORLDWIDE.

HOSPITALS, FDA AND MFR’S ALL FAILED IN THEIR RESPONSIBILITY TO REPORT, NOTIFY AND ACT ON KNOWLEDGE THAT OUTBREAKS WERE OCCURRING.

Published Duodenoscope / CRE Outbreaks
Illinois 2013 – 156 patients exposed to CRE/ 39% transmission rate/ 6 deaths
Washington 2014 - 39 cases/ 18 deaths
Pennsylvania 2013 – 4 deaths
Wisconsin 2014 – 3 deaths
California – 2014 - 2 deaths + other media reports

New, large epidemiological study by researchers at Johns Hopkins University; Baltimore, Maryland

- ANALYZED DATA FROM SIX STATES: FL, NY, GA, NE, VT, CA
- COMPARED OUTCOMES IN DIVERSE SETTINGS: ASCS, EDS, IN-PATIENT
- FOR NEW POST-PROCEDURAL INFECTIONS REQUIRING TX WITHIN 7 DAYS

<table>
<thead>
<tr>
<th>Procedure</th>
<th>N</th>
<th>Infections per 1000 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammogram (negative control)</td>
<td>647,212</td>
<td>0.6</td>
</tr>
<tr>
<td>Screening colonoscopy</td>
<td>462,068</td>
<td>1.1 (range: 0-115/1000)</td>
</tr>
<tr>
<td>Non-screening colonoscopy</td>
<td>914,140</td>
<td>1.6 (range: 0-132/1000)</td>
</tr>
<tr>
<td>Upper GI endoscopy</td>
<td>873,138</td>
<td>3.0 (range: 0-62/1000)</td>
</tr>
<tr>
<td>Cystoscopy*</td>
<td>68,432</td>
<td>4.4</td>
</tr>
<tr>
<td>Bronchoscopy**</td>
<td>30,116</td>
<td>15.6</td>
</tr>
</tbody>
</table>

WHO-Definition of Risk

<table>
<thead>
<tr>
<th>Definition</th>
<th>Range (proportion)</th>
<th>Range (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very common</td>
<td>More than 1/10</td>
<td>&gt;10%</td>
</tr>
<tr>
<td>Common</td>
<td>From 1/100 to 1/10</td>
<td>1% - 10%</td>
</tr>
<tr>
<td>Uncommon</td>
<td>From 1/1000 to 1/100</td>
<td>.1% - 1%</td>
</tr>
<tr>
<td>Rare</td>
<td>From 1/10,000 to 1/1000</td>
<td>.01% - .1%</td>
</tr>
<tr>
<td>Very rare</td>
<td>Fewer than 1/10,000</td>
<td>.001% - .01%</td>
</tr>
</tbody>
</table>

Note: *Includes only non-UTI infections and ** includes only non-respiratory infections

Source: Wang et al., Gut, 2018


3M Confidential
Patient Outcomes for post-endoscopy infections

FOR PATIENTS WITH INFECTIONS:

• >60% required hospitalization
• ~8 day mean length of stay

Deaths occurred:

• 0.4% for screening colonoscopy
• 1.7% for non-screening colonoscopy
• 2.6% for upper GI procedures
• Not reported for cystoscopy or bronchoscopy

Source: Wang et al., Gut, 2018
New Guidelines Issued


AAMI: Association for Advancement of Medical Instrumentation

AORN: Association of periOperative Registered Nurses

ASGE: American Society for Gastrointestinal Endoscopy/ Multisociety update

CDC/HICPAC: Healthcare Infection Control Practices Control Advisory Committee + FDA/CDC/ASM Culture protocols


France: Technical Guide. Handling of flexible, heat-sensitive endoscopes with channels (Ministry of Health and Social Affairs, 2016)

Others – older than 2016 including ESGE

To varying level of detail, guidelines agree on:

- Implement a quality system

- Follow manufacturer’s revalidated instructions for use

- Comprehensive training & competency

- Periodic review of policies and procedures

- Special attention to manual cleaning

- Use or assessment of cleaning verification (AORN, AAMI, SGNA, Italy, APSIC)
  - US facilities >50% using cleaning verification indicators*

- Most recommend periodic microbial surveillance
Clinical Challenges of Flexible Endoscopes

- Complex Design
- Minimally Invasive Surgery
- Critical Use Increases Patient Risk
- Heavily Soiled
- Easily Damaged

## Confusion on Basic Definitions

<table>
<thead>
<tr>
<th>Cleaning</th>
<th>High-Level Disinfection (HLD)</th>
<th>Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Removal of organic soil</td>
<td>• Microbial kill under defined conditions</td>
<td>• Kills all living organisms including spores</td>
</tr>
<tr>
<td>• Microbes and soil still be present</td>
<td>• All spores are not killed</td>
<td>• Dependent on cleaning</td>
</tr>
<tr>
<td>• Device is still contaminated</td>
<td>• Dependent on effective cleaning and drying</td>
<td>• Dry, sterile packaged item (terminal)</td>
</tr>
</tbody>
</table>
## Challenge to Consistently Follow Guidelines

<table>
<thead>
<tr>
<th>Observed Activity</th>
<th>Steps Completed (%)</th>
<th>(n = 69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>➢ Leak test performed in clear water</td>
<td>77</td>
<td></td>
</tr>
<tr>
<td>➢ Disassemble endoscope completely</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>➢ <strong>Brush all endoscope channels and components</strong></td>
<td>43</td>
<td></td>
</tr>
<tr>
<td>➢ Immerse endoscope completely in detergent</td>
<td>99</td>
<td></td>
</tr>
<tr>
<td>➢ Immerse components completely in detergent</td>
<td>99</td>
<td></td>
</tr>
<tr>
<td>➢ Flush endoscope with detergent</td>
<td>99</td>
<td></td>
</tr>
<tr>
<td>➢ Rinse endoscope with water</td>
<td>96</td>
<td></td>
</tr>
<tr>
<td>➢ Purge endoscope with air</td>
<td>84</td>
<td></td>
</tr>
<tr>
<td>➢ Load and complete automated cycle for high-level disinfection</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>➢ Flush endoscope with alcohol</td>
<td>86</td>
<td></td>
</tr>
<tr>
<td>➢ <strong>Use forced air to dry endoscope</strong></td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>➢ Wipe down external surfaces before hanging to dry</td>
<td>90</td>
<td></td>
</tr>
</tbody>
</table>

Multiple steps skipped 45% of the time.

Manual cleaning and automated high-level disinfection done correctly only 1.4% of the time.

ECR (automated cleaning and disinfection) performed correctly 75.4% of the time.

Ofstead, Cori L., Wetzler, Harry, P., Alycea Snyder, Rebecca A. Horton
2010 Gastroenterology Nursing. Vol 33, No. 4, pp. 304-311

126 steps in updated duodenoscope IFU
Follow a comprehensive QC program to include:

1. Product identification and traceability
2. Documentation and record-keeping
3. Verification and monitoring of the cleaning process
4. Monitoring of high-level disinfection and sterilization processes
5. Product recalls
6. Quality process improvement
Focus on Manual Cleaning

• Long term recognized problem

• It is critical to success of HLD and Sterilization

• Lack of proper manual cleaning contributed to outbreaks

• Standards recommending measurement with validated, real-time, quality control indicators for cleaning efficacy
  - Commercially available kits that test for ATP, protein, hemoglobin, carbohydrate
Cleaning = Effective Removal of Clinical Soil

Removes clinical soil:
• Tissue
• Blood and other body fluids
• Bacteria
• non-organics

Required for:
• Effective HLD or sterilization

Quantifiable:
• Established benchmarks
• Facility improvement
Components Found in Clinical Soil

To measure effectiveness of cleaning - a soil component is selected to measure.
Principle of ATP Bioluminescence Technology

Converts ATP to a light signal

Fire-fly enzyme Luciferase uses ATP to produce Light

\[ \text{ATP} + O_2 \rightarrow \text{Luciferin} + \text{Light} + CO_2 \]

Simple Relationship

Increase amount of light (RLU - reading)
Increase level of femtomoles of ATP (unit of measure)
Increase organic contamination
## Comparison of Common Cleaning Verification Indicators

<table>
<thead>
<tr>
<th>ATP</th>
<th>Protein</th>
</tr>
</thead>
<tbody>
<tr>
<td>Universal Marker</td>
<td>Universal Marker</td>
</tr>
<tr>
<td>Mature technology</td>
<td>Mature technology</td>
</tr>
<tr>
<td>Commerially available</td>
<td>Commerially available</td>
</tr>
<tr>
<td>Rapid tests are objective, numeric</td>
<td>Rapid tests are subjective, colorimetric</td>
</tr>
<tr>
<td>ATP is stable under reprocessing conditions</td>
<td>Rapid tests cannot measure proteins that are denatured under reprocessing conditions.</td>
</tr>
<tr>
<td>Will detect microbial ATP</td>
<td>Does not detect microbial proteins: requires additional sample prep for detection</td>
</tr>
<tr>
<td>Cannot be used when prions are an issue</td>
<td>Used when prions are an issue</td>
</tr>
<tr>
<td>Different manufacturer’s use different measurement scales so cannot compare different systems.</td>
<td>Measurement scale is in standardized µg</td>
</tr>
</tbody>
</table>
STANDARD CLEANING MARKER BENCHMARKS:

**PROTEIN**: ≥ 6.4 mg/cm²

COLOR CHANGE INDICATORS SHOULD CHANGE AT THIS LEVEL

CITATION: AAMI TIR30, ISO 15883

**ATP**: PUBLISHED VALIDATION: 200 RLU FOR COLONOSCPES AND GASTROSCOPES

RLU THRESHOLD VARIES BY MANUFACTURER RELATED TO PRODUCT DESIGN

EACH MANUFACTURER VALIDATES THRESHOLD

FACILITIES OFTEN CAN EXCEED THAT LEVEL

**NOTE**: ATP BENCHMARKS IN FEMTOMOLE UNIT OF MEASURE (NORMALIZED AMONG MANUFACTURERS)

**HEMOGLOBIN**: < 1.0 mg/cm²

COLOR CHANGE INDICATORS SHOULD CHANGE AT THIS LEVEL
Terminal Sterilization of Flexible endoscopes
1. PUBLISHED EVIDENCE OF OUTBREAKS AND CONTAMINATION (SEE REFERENCES)
2. EVIDENCE TERMINAL STERILIZATION HALTED OUTBREAKS (EPSTEIN, SMITH, ETC.)
3. LOCATION OFTEN DETERMINES PRACTICE (OFSTEAD)
4. INCONSISTENT GUIDELINES
5. ENDOSCOPE DAMAGE COMMON (OFSTEAD)
6. SOIL/BIOBURDEN REQUIRES FRICTION (ALFA)
7. DRYING INEFFECTIVE (OFSTEAD)
8. NON-MEDICAL ‘HELPERS’ IMPEDES CLEANING (OFSTEAD)
9. HIGH COST TO SYSTEM TO IMPROVE (IAHCSMM)
10. PROPOSED CHANGE TO CLASSIFICATION (RUTALA, OTHERS)
Proposed Change to Classification – not accepted

CRITICAL: Devices which directly or secondarily (i.e. via mucous membrane such as a Duodenoscope, cystoscope, bronchoscope) enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

SEMICRITICAL: Devices that come in contact with mucous membranes or non-intact skin but does not penetrate them.

Recognition flexible endoscopes are often used as critical devices.

Source: Berry and Kohn OR Technique 2016

Source: Dr. William Rutala, USA APIC 2017, AJIC 2016:44
www.Sterilizationanddisinfection.org
How do we know terminal sterilization helps?
Published Evidence in Peer Reviewed publications

Outbreak first reported in CDC MMW Jan 2012; No breach in reprocessing with HLD identified;

Resolution: Ethylene oxide ‘...(gas) sterilization contributed to controlling this outbreak....’

Epstein et al. JAMA 2014; 312:1447-1455

Review of procedures revealed that all standard recommendations and guidelines followed;

Resolution: “After EtO sterilization of all duodenoscopes, no additional cases of CRE infection were diagnosed”.


University of Pittsburgh Medical Center; No breach in reprocessing with HLD identified;

Resolution: “No additional healthcare-associated infections have been noted since ERCP/EUS scope reprocessing included ETO “


Impact of ethylene oxide gas sterilization of duodenoscopes after a carbapenem-resistant Enterobacteriaceae outbreak.

Resolution: “the addition of ETO...with cultures reduced duodenoscope contamination and eliminated clinical infections

<table>
<thead>
<tr>
<th>Definitions</th>
<th>Source</th>
<th>Definition</th>
<th>Processes types</th>
<th>Key Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sterilization</strong></td>
<td>FDA</td>
<td>Validated process used to render a product free from viable microorganisms.</td>
<td>Thermal – saturated Steam, dry heat</td>
<td>Exhibit log linear kill kinetics.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sterility is determined by the probability of surviving organism.</td>
<td>Chemical – EO, VHP, Ozone, VHP+Oz, Formaldehyde</td>
<td>SAL validated and defined by FDA.</td>
</tr>
<tr>
<td><strong>Terminal Sterilization</strong></td>
<td>FDA</td>
<td>Product is sterilized within its sterile barrier system.</td>
<td>As above</td>
<td>Packaging system must also be validated.</td>
</tr>
<tr>
<td><strong>Liquid Chemical Sterilant System</strong></td>
<td>FDA</td>
<td>Immediate use system that utilizes a liquid chemical sterilant (LCS) which is a chemical solution that has been validated to provide microbial kill adequate to obtain FDA clearance for a sterilization label claim.</td>
<td>PAA</td>
<td>Do not exhibit log linear kinetics. Shape of the survivor curve can vary depending on the formulation, chemical nature, and stability.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Other LCS with long exposure</td>
<td>Qualitative based on kill end points.</td>
</tr>
</tbody>
</table>
Microbiocidal Practices for Flexible Endoscopes

**HIGH LEVEL DISINFECTION**
- Designed to kill 6 logs of various test organisms
- Does not kill all spores

**LIQUID CHEMICAL STERILIZATION**
- Designed to kill 6 logs of various test organisms
- Spore kill required

**TERMINAL STERILIZATION**
- Designed to kill 12 logs
  - Provides sterilization assurance level (SAL $10^{-6}$)
  - Absence of life (includes all spores)

\[
1,000,000 = 10 \times 10 \times 10 \times 10 \times 10 \times 10 = 10^6 \\
\times 2 = 2,000,000?
\]

\[
1,000,000,000,000 = 10 \times 10 \times 10 \times 10 \times 10 \times 10 \times 10 \times 10 \times 10 \times 10 \times 10 = 10^{12}
\]
Terminal Sterilization Validation Requirement

- Terminal - sterilizer + packaged
- Validated process measured by kill of most resistant organism
- Process achieves an SAL of $10^{-6}$ SAL - 12 logs of bacterial spore kill

Demonstrates log linear kill kinetics = predictable lethality

Margin of Safety refers to OVERKILL SAFETY Factor in Terminal Processes

Source: ANSI/AAMI ST58; 2013
## Sterilization Options and Limitations by Process Types

<table>
<thead>
<tr>
<th>Process</th>
<th>VH2O2 w or w/o Plasma</th>
<th>VH2O2 + Ozone</th>
<th>Ethylene Oxide</th>
<th>Liquid Chemical Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Damage from high temp or moisture</td>
<td>Not in IFU (GI scopes)</td>
<td>Not in IFU</td>
<td>No limitations on channel length and inner diameter</td>
<td>Designed to kill spores</td>
</tr>
<tr>
<td>Limitations on channel length and inner diameter</td>
<td>Limitations on channel length, inner diameter, load weight</td>
<td>Limitation on lumen number</td>
<td>History of safe use for flexible endoscopes</td>
<td>Not in IFU</td>
</tr>
<tr>
<td>Oxidative</td>
<td>High cost</td>
<td>Highly oxidative chemistry</td>
<td>Long aeration times</td>
<td>JIT process/ stored = HLD only</td>
</tr>
<tr>
<td>High cost</td>
<td></td>
<td>High cost</td>
<td>Employee monitoring</td>
<td>No published evidence LCS helped to control outbreaks</td>
</tr>
<tr>
<td>Oxygen in environment</td>
<td></td>
<td>Oxygen in environment</td>
<td>Limited access*</td>
<td></td>
</tr>
</tbody>
</table>

*Designed to provide a sterility assurance level (SAL) of $10^{-6}$*
## Search for Ideal Low Temp Sterilant

<table>
<thead>
<tr>
<th>Attribute</th>
<th>HLD</th>
<th>LCS</th>
<th>EO</th>
<th>VH202</th>
<th>VH202 + O2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overkill – Margin of Safety</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Efficacy long lumens</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>In IFU</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Materials compatible</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Rapid</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
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<td>Soil tolerant</td>
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<td>✗</td>
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</table>
The Other Challenging, Important Steps

Cleaning
- Clinical soil must be reduced

Inspection for damage
- Damage impacts biofilm and ability to clean

Drying
- Little evidence of what is effective
- Must be dry!

Photo credits: 3M, Healthmark, BHT
Conclusions & Recommendations

• Flexible Endoscopy is NOT a low risk procedure

• Quality and effectiveness of endoscope reprocessing is inconsistent

• Implement validated, real-time cleaning verification for routine QC
  – Use rapid, cleanliness monitors (ATP, protein, other)

• Microbial surveillance should be used as an audit tool

• Terminal sterilization for all endoscopes used in critical procedures:
  • Enter normally sterile tissue / organs or enter vascular system
Thank you for your time and attention
Email: jmprust1@mmm.com
References


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