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VIRTUAL SYMPOSIUM STARTING SOON

Transforming Endoscope Reprocessing:

Introducing a first-ever paradigm shift for in-hospital terminal sterilization.

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Bill Rutala, PhD, MPH, CIC

A Paradigm Shift: Transition from HLD to Sterilization of Endoscopes

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A Paradigm Shift:
Transition from HLD to Sterilization of Endoscopes

William A. Rutala, Ph.D., M.P.H., C.I.C.

Director, Statewide Program for Infection Control and Epidemiology and
Professor of Medicine, University of North Carolina at Chapel Hill, NC, USA

Former Director, Hospital Epidemiology, Occupational Health and Safety, UNC
Health Care, Chapel Hill, NC (1979-2017)

Disclosures: PDI, Kinnos, Ideate Medical

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More infections are associated with endoscopes (and other semi-critical items) than with any other medical or surgical item in health care

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A Paradigm Shift:
Transition from HLD to Sterilization of Endoscopes

- Why shift from HLD to sterilization
- Reduce infection risk associated with HLD of endoscopes
- FDA and professional organizations support shift to sterilization

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Disinfection and Sterilization

Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643.

EH Spaulding believed that how an object will be disinfected depended on the object's intended use.

CRITICAL - objects which enter normally sterile tissue (e.g., duodenoscope [duodenum], cystoscope [bladder], bronchoscope [lung]) or the vascular system or through which blood flows should be sterile.

SEMICRITICAL - objects that touch mucous membranes or skin that is not intact require a disinfection process (high-level disinfection [HLD]) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL - objects that touch only intact skin require low-level disinfection (or non-germicidal detergent).

Why Shift from HLD to Sterilization

Rutala, Weber. AJIC 2023;51:A96-A106

Many reasons sterilization is superior to standard HLD in reducing the risk of microbial contamination and infection to include:

- Comply with Spaulding classification scheme
- Evidence-based recommendation as more than 150 outbreaks
- No margin of safety associated with HLD (10^{10} microbes vs $\geq 10^{6}$ Cleaning and HLD)
- Sterilization can improve outcomes as it can be validated (BI) and provides a SAL
- Some HLD are relatively resistant to atypical mycobacteria
- No toxicity or anaphylactic reaction
- HLD is a complex process and prone to errors and challenges (1.4% compliance with 12 steps)

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Infections/Outbreaks Associated with Semicritical Medical Devices

Rutala WA, Weber DJ. Am J Infect Control. 2019 Jun;47S:A79-A89.

- HBV and HCV transmission during endoscopy and use of semicritical medical devices can occur, but it is rare (3)
- No articles related to possible transmission of HIV via medical device
- Greatest evidence of transmission associated with GI endoscopes/bronchoscopes(~150 outbreaks) likely due to microbial load and complexity.
- Several other semicritical medical devices are associated with infections related to inadequate reprocessing

Table 2
Infections and outbreaks associated with semicritical medical devices*

Instruments	# Outbreaks/ Infections	# Outbreaks/ Infections with bloodborne pathogens
Vaginal probes	0**	0
Nasal endoscopes	0	0
Hysteroscopes	0	0
Laryngoscopes	2[43-45]	0
Urologic instrumentation (eg, cystoscopes, ureteroscopes)	8[46-53]	0
Transrectal-ultrasound guided prostate probes	1[40]	0
Transesophageal echocardiogram	5[51,54-57]	0
Applanation tonometers	2[41,42]	
GI endoscopes/bronchoscopes	~130[7,8]	3 HBV[34]; HCV[35,36]

GI, gastrointestinal; *HBV*, hepatitis B virus; *HCV*, hepatitis C virus.
*These infections/outbreaks were found in the peer-review literature through PubMed and Google.
**Does not include outbreaks associated with contaminated ultrasound gel used with vaginal probes or transmission via health care personnel.

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Why Shift from HLD to Sterilization

Rutala, Weber. AJIC 2023;51:A96-A106

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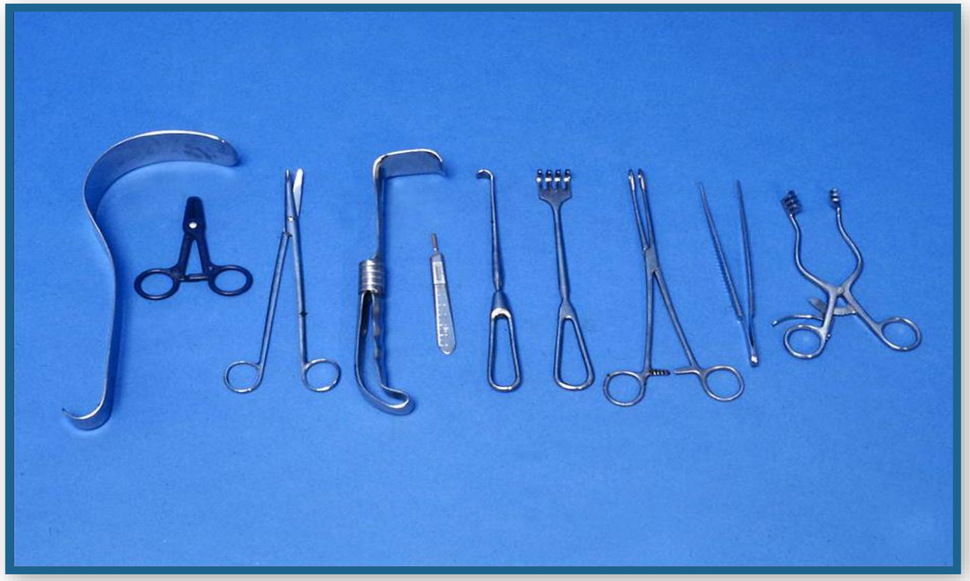
Endoscope Reprocessing Challenges

Complex [elevator channel, long, narrow lumens]-10^{7-10} bacteria/endoscope

Surgical instruments - $<10^{2}$ bacteria, 85%



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Reason for Endoscope-Related Outbreaks

Rutala et al. AJIC 2023;51:A97-A106 ; Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- **Infection risk-no margin of safety with endoscope reprocessing**
- **Microbial load**
  - GI endoscopes contain $10^{7\text{-}10}$ (7-10 logs)
  - Cleaning results in 2-6 $\log_{10}$ reduction
  - High-level disinfection results in 4-6 $\log_{10}$ reduction
  - Results in a total 6-12 $\log_{10}$ reduction of microbes
  - Level of contamination after processing: 4 $\log_{10}$ or 10,000 (maximum contamination-10^{10}, minimal cleaning/HLD-10^{6})
- **Complexity of endoscope and endoscope reprocessing**
- **Biofilms-could contribute to failure of endoscope reprocessing**

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What Is the Public Health Benefit?

Rutala et al. AJIC 2023;51:A96-A106

Margin of Safety-currently nonexistent (10^{10} on endoscope, HLD kills $\geq 10^{6}$); sterilization will provide a safety margin (~6 $\log_{10}$). To prevent infections, all endoscopes should be devoid of microbial contamination.

HLD (≥6 $\log_{10}$ reduction)

vs

Sterilization (≥12 $\log_{10}$ reduction spores=SAL 10^{-6})

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Why Shift from HLD to Sterilization

Rutala, Weber. AJIC 2023;51:A96-A106

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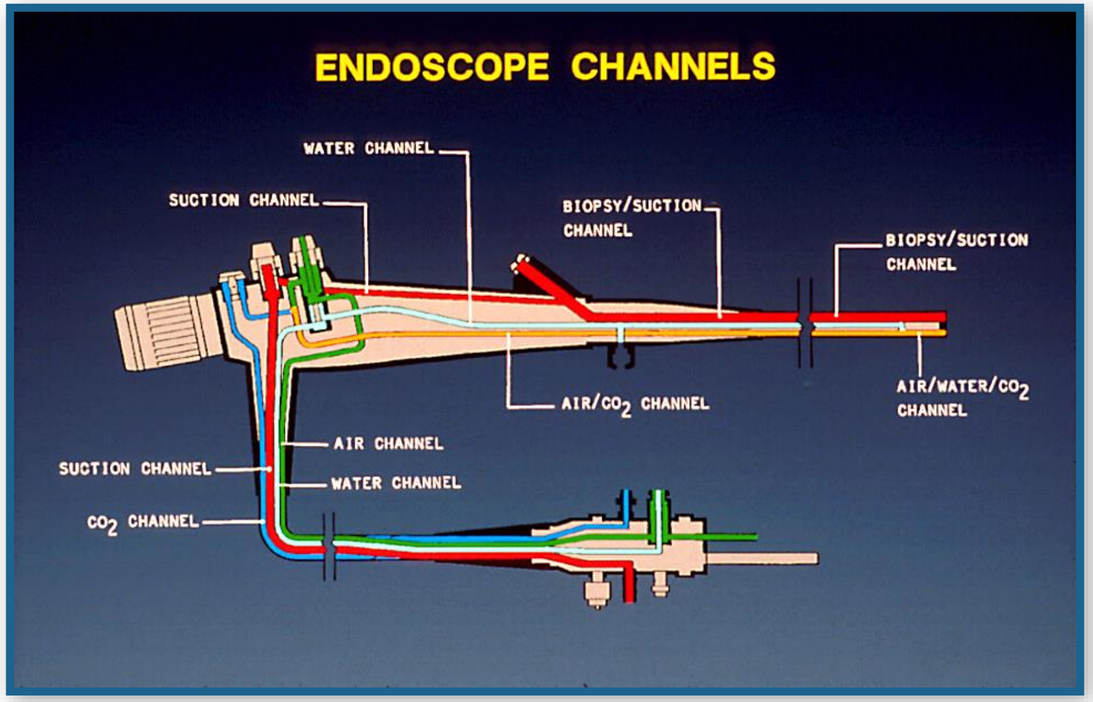
Features of Endoscopes that Predispose to Disinfection Failures

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- Heat labile
- Long, narrow lumens (3.5ft, 1-3mm)
- Right angle bends
- Rough or pitted surfaces
- Springs and valves
- Damaged channels may impede microbial exposure to HLD
- Heavily contaminated with pathogens, $10^{7\text{-}10}$
- Cleaning (2-6 10-$\log_{10}$ reduction) and HLD (4-6 10-$\log_{10}$ reduction) essential for patient safe instrument



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Why Shift from HLD to Sterilization

Rutala, Weber. AJIC 2023;51:A96-A106

Many reasons sterilization is superior to standard HLD in reducing the risk of microbial contamination and infection to include:

- Liability arising from an unquantifiable process that results in uncertainty
- Evidence emerging about biofilm resistance to high-level disinfectants
- High-level disinfected items are unpackaged and can become recontaminated, terminal sterilization prevents contamination
- Environmental contamination during drying, handling and storage
- A shift from HLD to sterilization would provide a safety margin

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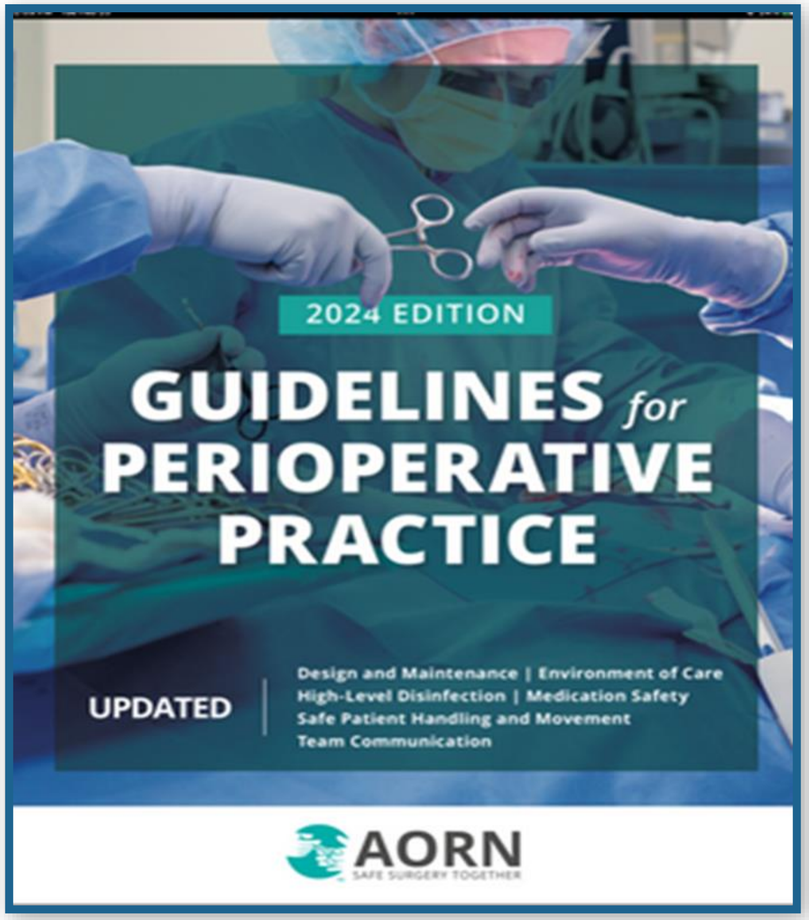
Sterilize reusable flexible endoscopes that are manufacturer validated for sterilization when possible. *[Recommendation]*



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With the infection risk that endoscopes present to the patient, sterilization is the preferred method of microbial inactivation and the only option for instruments to be used in “critical” uses entering sterile body cavities, tissues, or vascular spaces. Sterilization continues to be recommended for endoscopes. Terminal sterilization is also required for all endoscope accessories that penetrate the mucosa, such as biopsy forceps, sphincterotomes, etc. When sterilization is required, most endoscopes require low temperature sterilization. Compatibility with low-temperature sterilization processes varies with endoscope make and model. Compatible processes can include ethylene oxide (EO), hydrogen

34. Instead of HLD, should certain semi-critical devices preferentially be sterilized?

Recommendation:

1. When sterilization technologies are shown to be effective in clinical settings and cycle specifications are validated and included in the MIFU, facilities should begin developing an institutional process for converting from HLD to sterilization for semi-critical reusable medical devices that are associated with a high risk of transmission of infection to patients.

Infection Control & Hospital Epidemiology (2025), **46**, 561–583
doi:10.1017/ice.2025.41

SHEA

SHEA Expert Guidance

Multisociety guidance for sterilization and high-level disinfection

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Abstract

SHEA, in partnership with ASGE, APIC, AAMI, AORN, HSPA, IDSA, SGNA, and The Joint Commission, developed this multisociety

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Why Shift from HLD to Sterilization

Rutala Weber, JAMA 2014; 312:1405-1406; Rutala, Weber. AJIC 2023;51:A96-A106

- National/international guidelines recommend sterilization for lumened endoscopic devices (AORN; AAMI)
- FDA has recommended sterilization for bronchoscopes rather than HLD when feasible (FDA, 2021)
- FDA has recommended sterilization for duodenoscopes (FDA Panel, 2015)
- FDA has precluded use of HLD for certain urologic endoscopes due to HLD failure…
  FDA recommends sterilization (FDA, 2022)
- FDA has promoted innovation to enhance safety (e.g., use of fully disposable, sterile duodenoscopes) (FDA, 2022)

If guidelines and the FDA recommend sterilization, why has sterilization of endoscopes not been implemented?

In general, sterilization technologies for reprocessing, reusable flexible endoscopes not available until now

(not-FDA cleared)

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FDA-Cleared Endoscope Sterilization Technology

Rutala, Weber. JAMA 2014. 312:1405-1406; Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643; Rutala, Weber. AJIC 2023;51:A96-A106

STERO SCOPE
STERILIZATION TECHNOLOGY

- **Sterilization of reusable endoscope**
  - Ideate Medical-HP Gas Plasma-SteroScope® FDA-cleared claims:
    - Terminal sterilization of cleaned reusable flexible endoscopes with up to 8 internal lumens with lumen dimensions of:
      - ID of 1.0 mm or larger and a length of 3580 mm or shorter and
      - ID of 1.2 mm or larger and a length of 4095 mm or shorter
    - FDA-cleared for terminal sterilization of 99% of the flexible endoscopes in the marketplace

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A Paradigm Shift:
Transition from HLD to Sterilization of Endoscopes

- Why shift from HLD to sterilization
- Reduce infection risk associated with HLD of endoscopes
- FDA and professional organizations support shift to sterilization

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Why Shift from HLD to Sterilization

Summary

- Endoscopes associated with more infections than any other medical or surgical instrument in health care
- No margin of safety associated with HLD due to high microbial load, complexity
- Recommendation to sterilize is evidenced-based
- Professional organizations (e.g., AAMI and AORN) recommend sterilization
- Based on safety communications, FDA favors innovative designs and sterilization for endoscopes
- Sterilization offers many potential benefits (e.g., validated, endoscope free from microbes, sterility assurance level, improved patient outcomes, reduced toxicity, instrument compatibility, reduced liability)
- Endoscope sterilization is a paradigm shift that enhances patient safety and efficacy

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Curtis Donskey, MD

Evaluation of a New Technology for Terminal Sterilization of Flexible Endoscopes Using Hydrogen Peroxide Gas Plasma

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Evaluation of a New Technology for Terminal Sterilization of Flexible Endoscopes Using Hydrogen Peroxide Gas Plasma

Curtis Donskey, M.D.

Louis Stokes VA Medical Center
Cleveland, Ohio

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Ideate Medical's SteroScope® Hydrogen Peroxide Gas Plasma Endoscope Sterilizer

- Sterilization of flexible endoscopes with as many as 8 internal channels
- The endoscope is placed inside a container that interfaces with the sterilizer and subsequently provides a sterile storage container for up to 6 months

STERO SCOPE
STERILIZATION TECHNOLOGY

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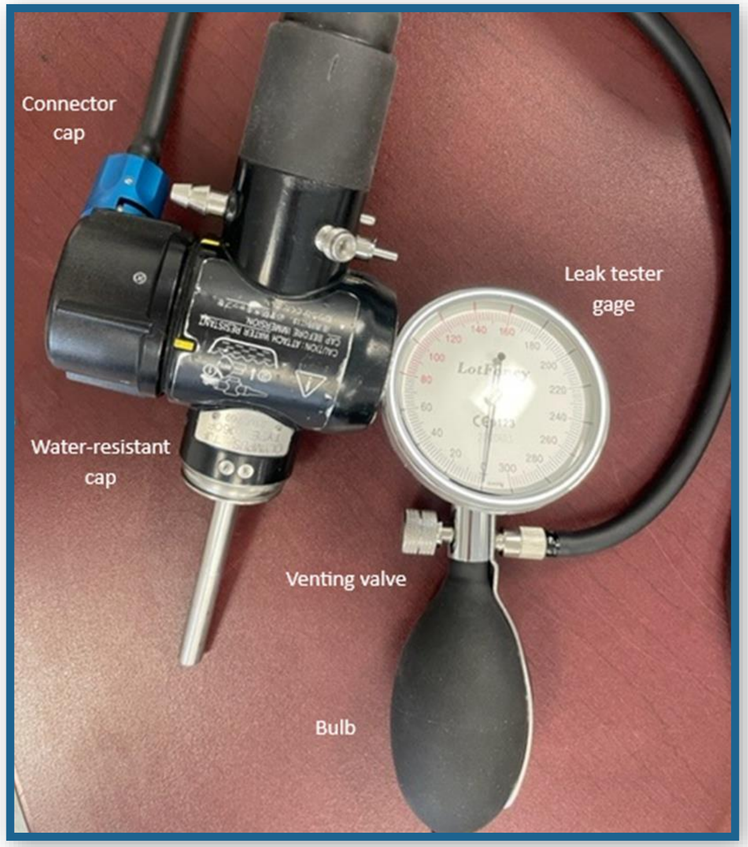
Ideate Medical's SteroScope®

- Prior to sterilization, manual cleaning is performed followed by drying with filtered forced air for >10 minutes
- The water-resistant cap must be removed from video endoscopes
- Leak test to ensure that there is no leak which could cause fluid invasion



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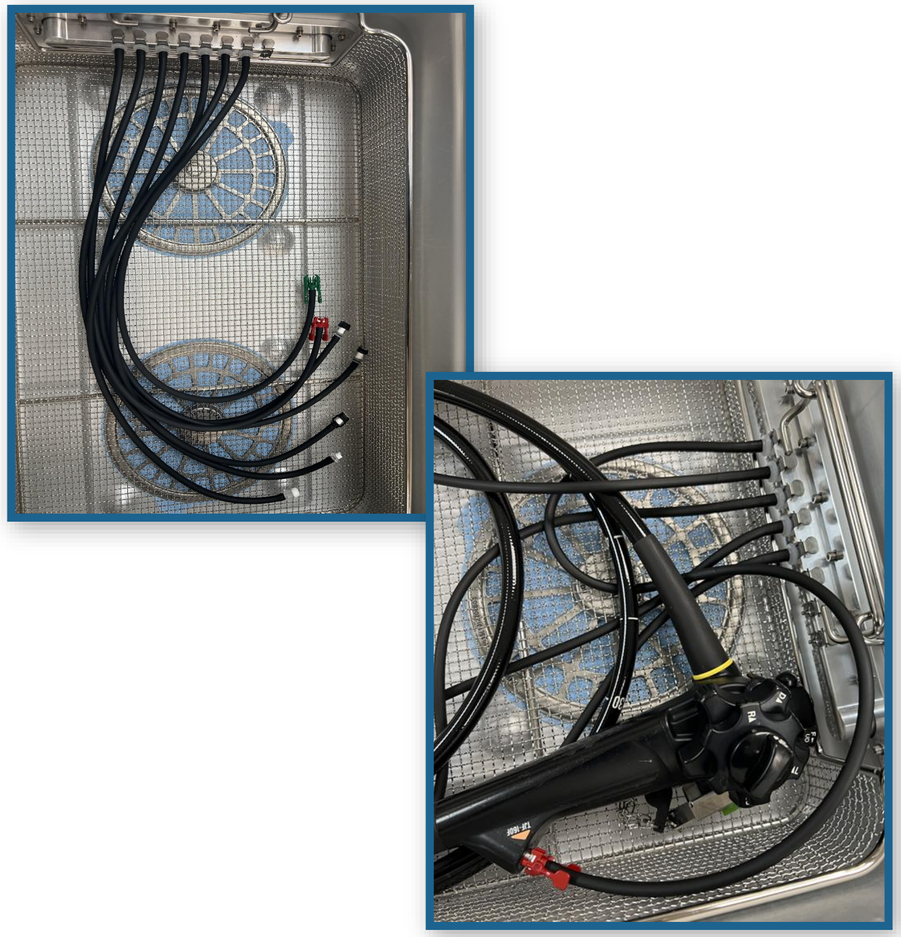
Ideate Medical's SteroScope®

- A single-use channel connector and pressure differential rapidly diffuses hydrogen peroxide gas plasma through the internal channels of the endoscope

- Each cycle requires a total of 44 minutes and includes 2 injections of hydrogen peroxide gas plasma 16 minutes apart



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FDA Requirements for Sterilization Validation

- To obtain FDA clearance, manufacturers required to provide evidence of a 6 $\log_{10}$ reduction in spores using a half-cycle with no soil and using a full cycle in simulated-use testing with soil

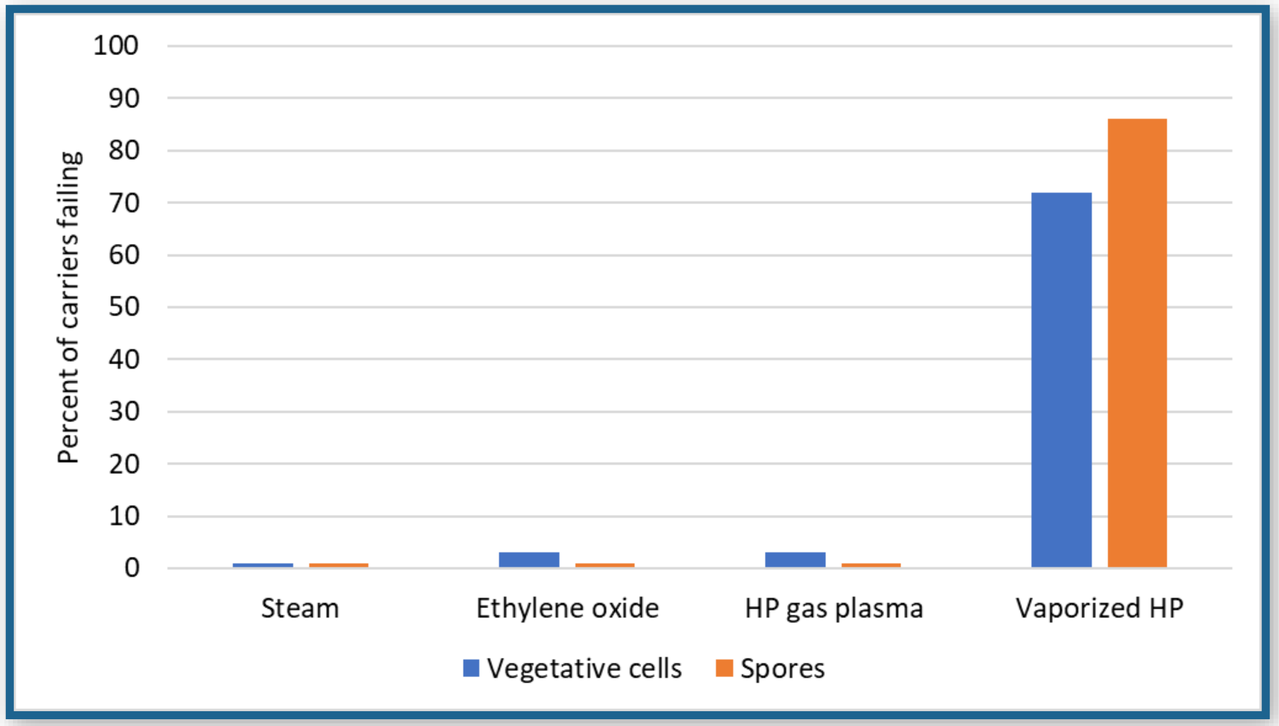
- An Olympus duodenoscope was sterilized 125 times with no evidence of damage to the scope

Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants. Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-and-format-premarket-notification-510k-submissions-liquid-chemical-sterilantshigh-level.

Testing by manufacturer

- Steel wires inoculated with 10^6 Geobacillus stearothermophilus spores with no soil placed in a duodenoscope elevator channel – 0 of 39 positive
- An Olympus duodenoscope was sterilized 125 times with no evidence of damage to the scope

Low-temperature sterilization technologies sometimes fail in the presence of salt and serum simulating inadequate cleaning



Soil: fetal calf serum and .29%-.65% salt

Rutala WA. Comparative evaluation of the microbicidal activity of low temperature sterilization technologies to steam sterilization. Infect Control Hosp Epidemiol 2020.

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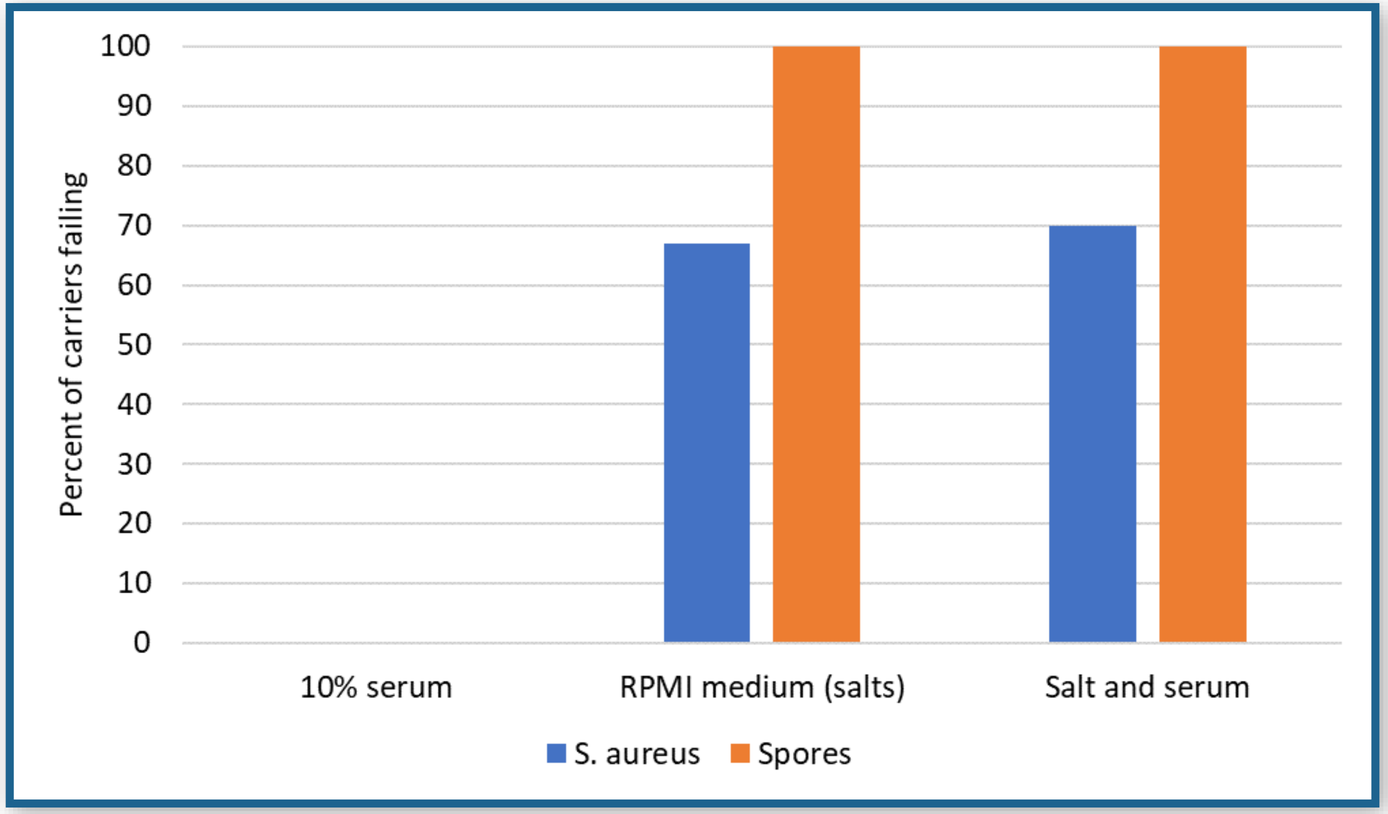
Salt was the principal factor interfering with efficacy



Rutala WA. Comparative evaluation of the microbicidal activity of low temperature sterilization technologies to steam sterilization. Infect Control Hosp Epidemiol 2020.

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Blood on dirty instruments interferes with low-temperature sterilization technologies

- Instruments: dirty (uncleaned) +/- blood
- Test organisms: bacteria, mycobacteria, spores
- Steam inactivated all organisms
- Ethylene oxide and hydrogen peroxide gas plasma frequently failed on dirty instruments both with and without blood

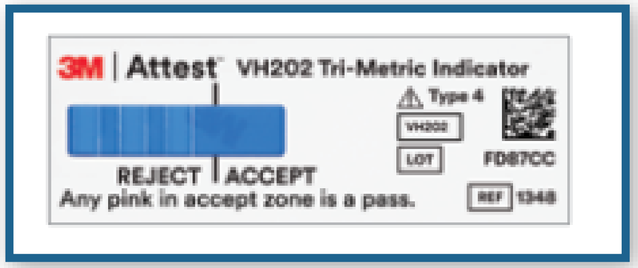
Rutala WA. Does blood on "dirty" instruments interfere with the effectiveness of sterilization technologies? Infect Control Hosp Epidemiol 2022.

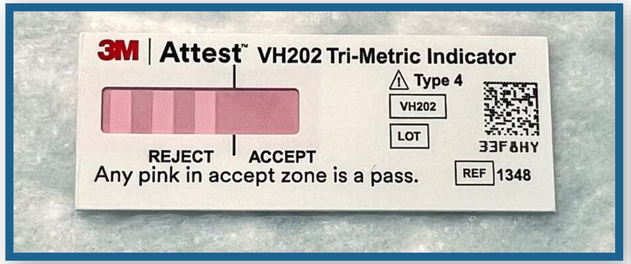
Objective

- Use multiple methods to evaluate the effectiveness of the sterilizer against spores and vegetative organisms with and without organic material and salt to simulate a worst-case scenario with inadequate cleaning

Chemical and biological indicators

- **3M Attest Vaporized Hydrogen Peroxide Type 4 Tri-Metric Chemical Indicators**
  - All indicated appropriate exposure time, temperature, and amount of hydrogen peroxide
- **3M Attest Super Rapid Vaporized Hydrogen Peroxide Biological Indicators (24 min)**
  - All with no surviving *G. stearothermophilus* spores





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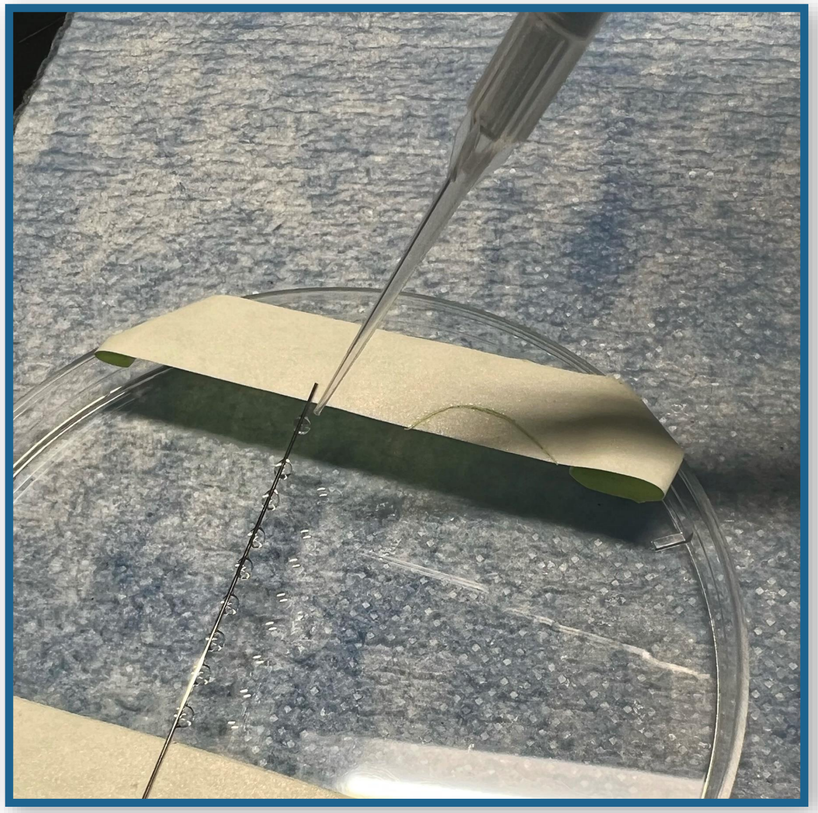
Test organisms

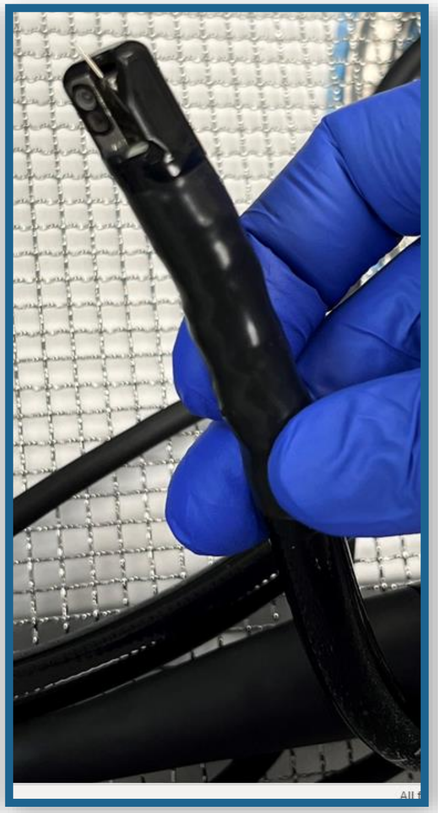
- **Vegetative organisms**
  - *Escherichia coli*, vancomycin-resistant *Enterococcus faecium* (VRE), *Candida auris*
  - Soil included for all tests
  - Inoculum: 8 to 9 $\log_{10}$ CFU
- **Spores**
  - *Bacillus atrophaeus*, *Clostridioides difficile*, *Clostridium sporogenes*
  - Inoculum: 6 to 9.7 $\log_{10}$ CFU

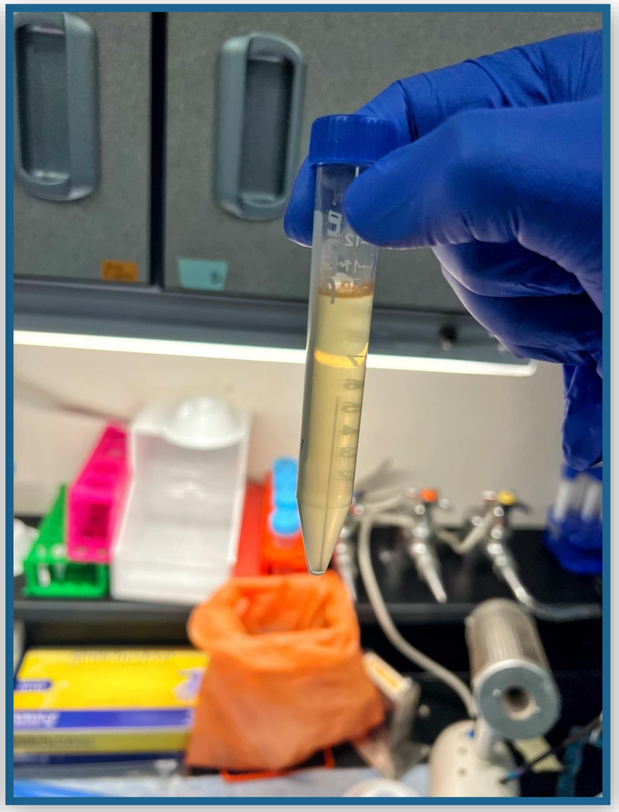
Test soils

- **5% fetal calf serum**
- **RPMI 1640 with ~0.65% salt and 10% fetal calf serum**
- **Artificial Test Soil (ATS)-2015**
  - Intended to simulate a “worst case” challenge
  - Salt base with mucin, insoluble cellulose fiber, reconstituted dried egg yolk, and 20% sterile sheep blood

Method 1. Inoculated steel wires placed inside elevator channel







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Method 2. Inoculation into the elevator recess and instrument channel with 5% serum

Flush with ~100 mL of sterile water to allow the inoculum to reach the center of the channel

Molloy-Simard V. Elevating the standard of endoscope processing: Terminal sterilization of duodenoscopes using a hydrogen peroxide–ozone sterilizer. AJIC 2019;47:243 - 250

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Method 3. Inoculation throughout the lumen using a brush

- Brush inserted into the biopsy port to the distal tip of the endoscope
- Immerse the distal tip of the duodenoscope in 20 mL of test organism suspension
- Elevator mechanism articulated 3 times
- Brush withdrawn from the biopsy port
- Process repeated 3 times
- Soil: 5% serum or ATS-2015

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Results

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Vegetative organisms

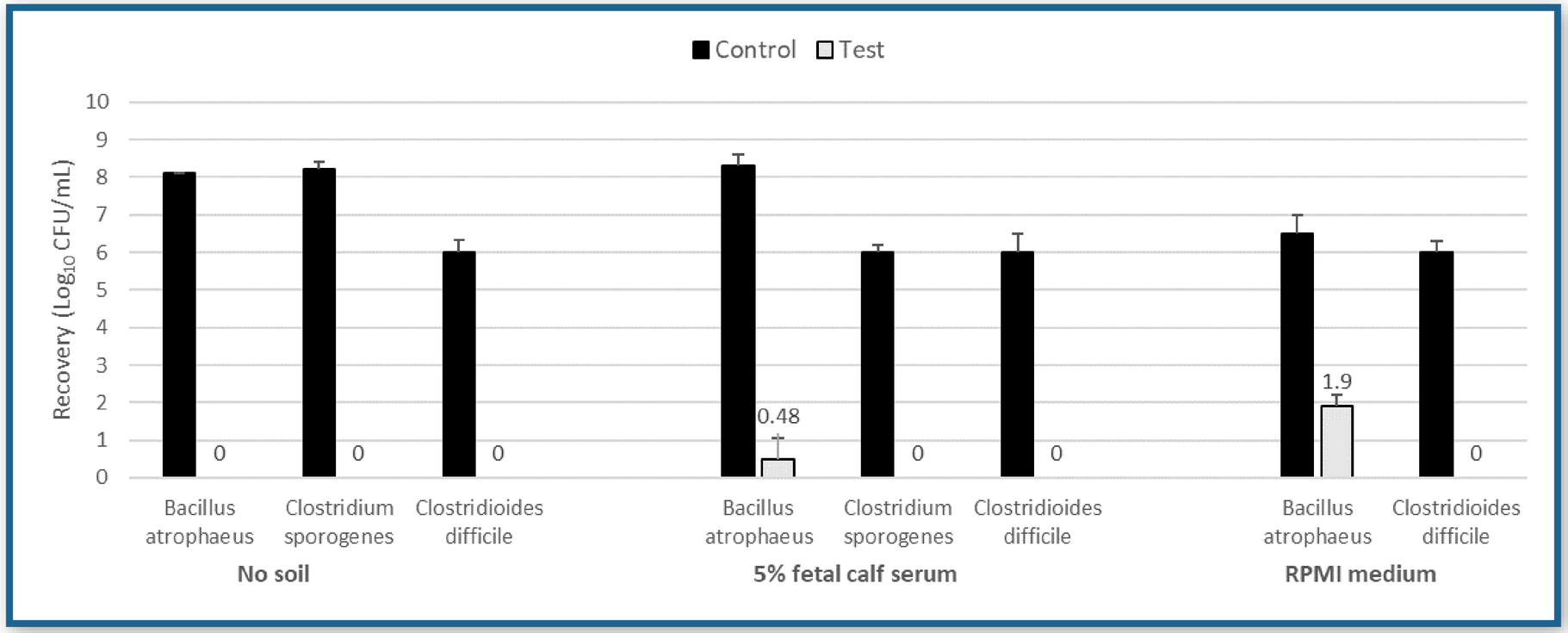
- For each test method and for all 3 test organisms, no organisms were recovered after sterilization
- Inoculum: 7.9 to 9.1 $\log_{10}$ CFU
- Soil: 5% serum, ATS-2015, and RPMI

Spores

- **No spores were recovered in the absence of soil**

- **In the presence of soil:**
  - 6.0 to 6.2 $\log_{10}$ spores consistently eliminated in accordance with the FDA requirement that no survivors are recovered after 6 $\log_{10}$ spore challenge
  - Low levels of spores were recovered when >6.5 $\log_{10}$ spores were recovered from the control endoscopes

Spores on inoculated steel wires



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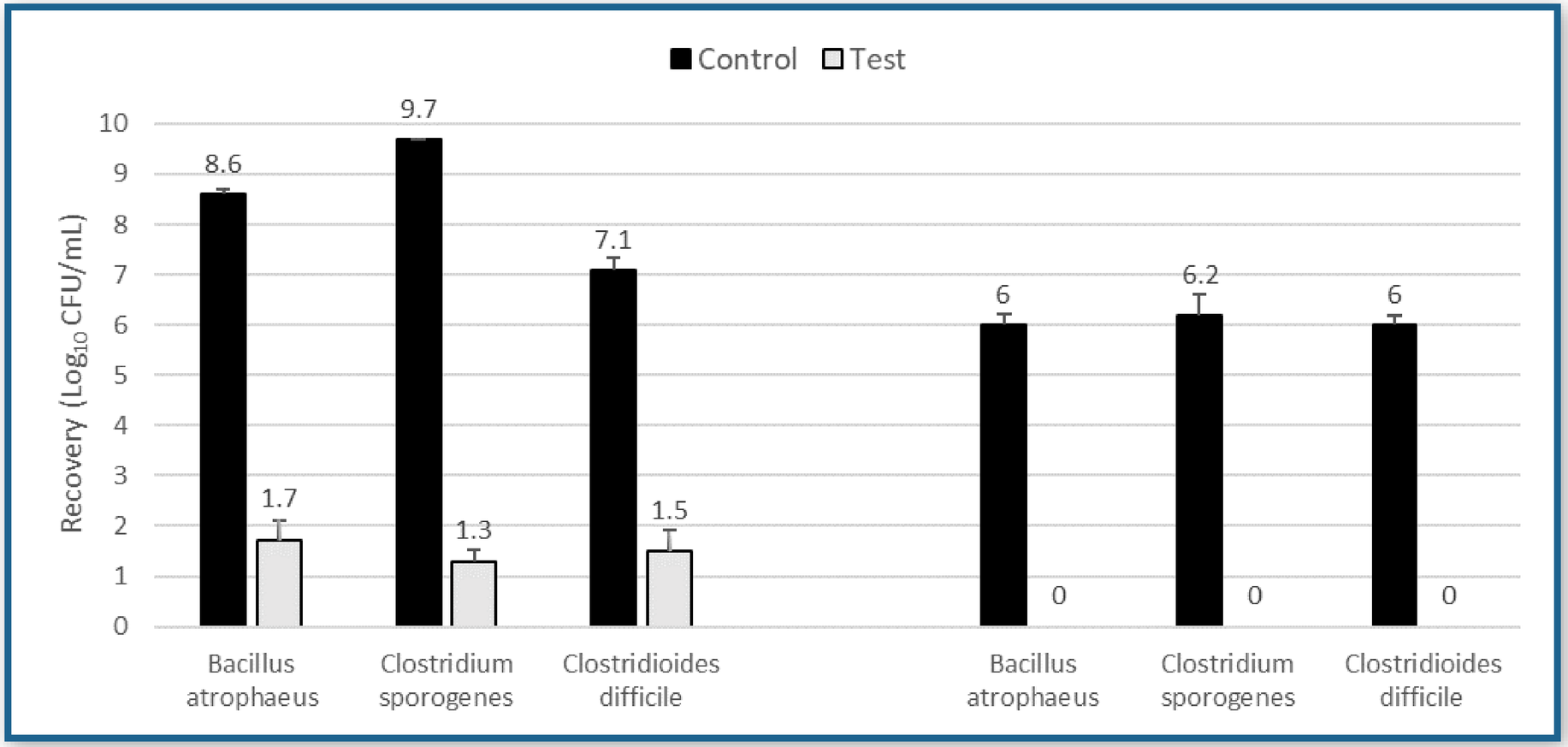
Spores inoculated in the elevator recess and instrument channel with 5% serum



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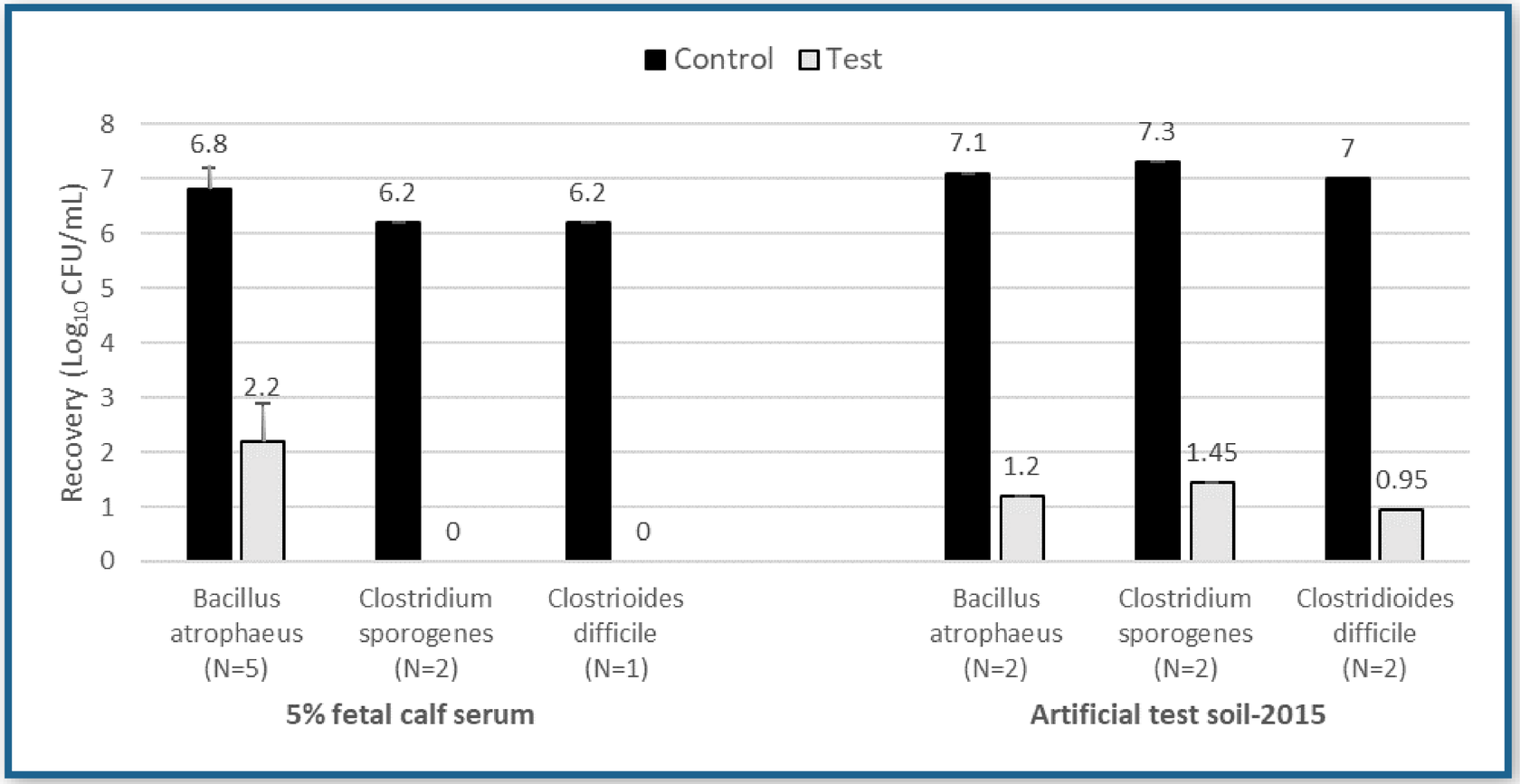
Spores inoculated throughout the lumen using a brush



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Summary

STERO SCOPE
STERILIZATION TECHNOLOGY

- The sterilizer consistently reduced vegetative organisms to undetectable levels even under “worst case” conditions including high organism load and presence of organic material and salts
- In the presence of a soil load, 6 $\log_{10}$ of spores were eliminated, but higher numbers of spores were not consistently eliminated
- These findings highlight the importance of meticulous cleaning of endoscopes prior to use of the sterilizer

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Kathleen McMullen

Evaluation Study of SteroScope®

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Evaluation Study of SteroScope®

KATHLEEN MCMULLEN

EXECUTIVE DIRECTOR, INFECTION PREVENTION AND HLD/STERILIZATION

STERO SCOPE
STERILIZATION TECHNOLOGY

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Evaluation Study

- **Small-scale experiment**
  - Introducing sterilization into an endoscopy area
  - Raise awareness of technology and implications
- **Goals:**
  - Understand potential alterations or disruptions to current process
  - Learn user impressions of these changes
  - Identify potential impact to physical space
  - Hear general lessons learned

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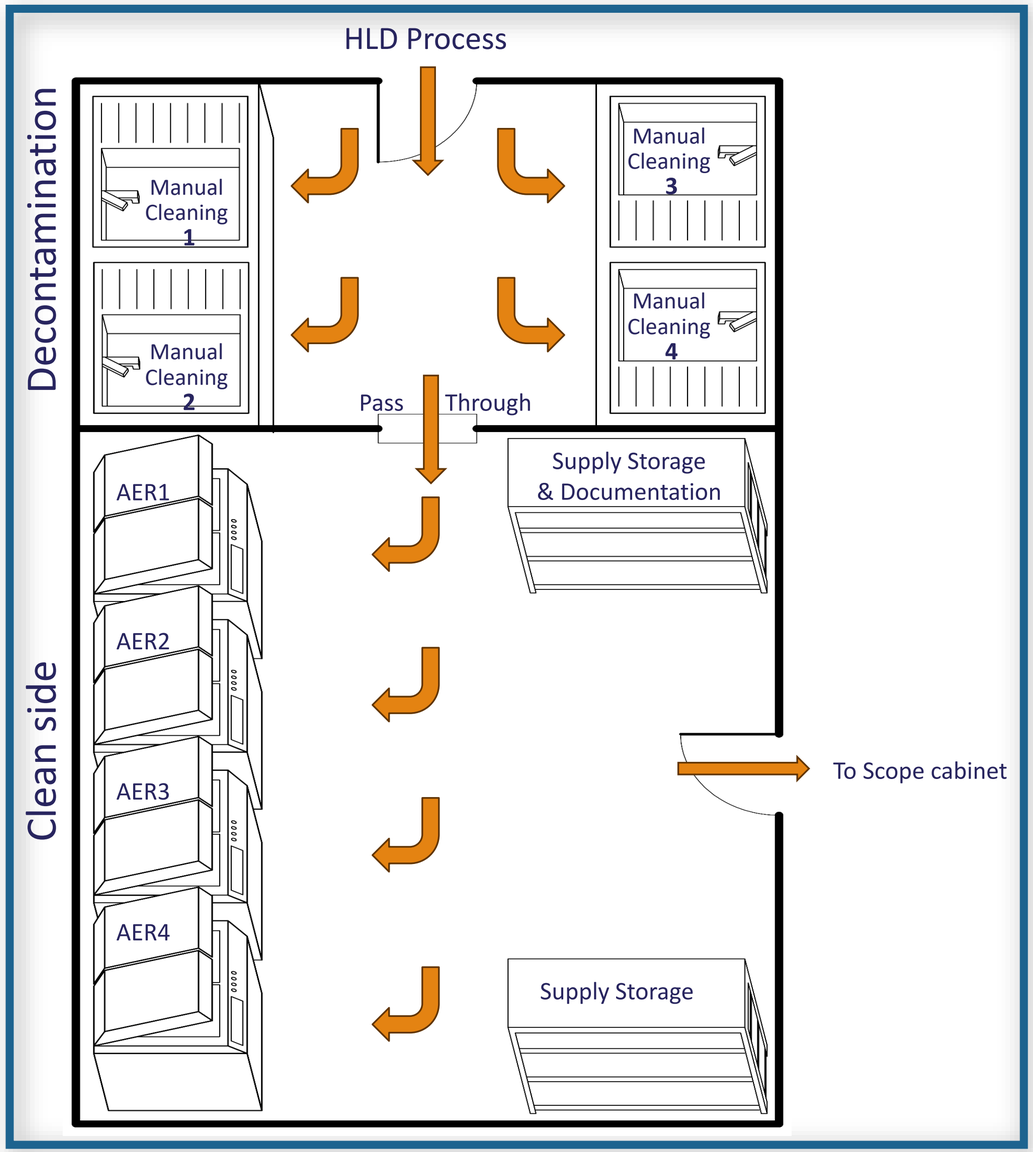
About Our Center

- **Mercy South: St. Louis area community-based acute care hospital**
- **25,000 procedures per year**
- **64 endoscopes**
- **8 endoscopy techs responsible for the various functions of scope re-processing**
- **2 room design, 4 automated endoscope reprocessers, horizontal-oriented endoscope drying cabinets**



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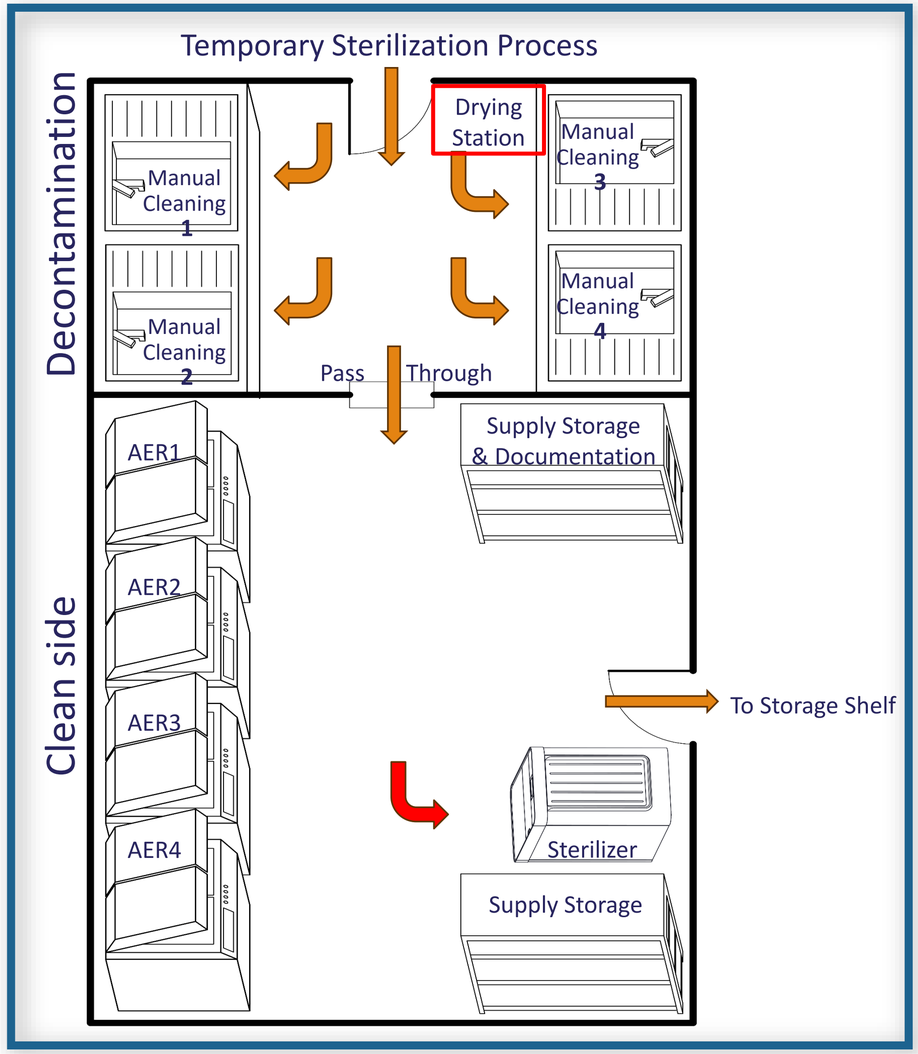
Study Details

- **1.5 weeks in April 2025**
- **30 sterilization cycles**
  - Olympus brand flexible endoscopes (9 GIF-H190L videogastroscope, 2 GIF-ITH190 gastrointestinal videoscope, 10 PCF-H190L video colonoscope, 5 CF-HQ190L video colonoscope and 4 TJF-Q190V duodenoscope)
- **At the elbow support from vendor**
- **Post study evaluations**

Workflow Differences

- **Same manual cleaning**
- **10 minutes of endoscope drying added**
- **Same pass through**
- **Sterilization:**
  - Scope connected to attachments in rigid container
  - Total cycle time of 43 minutes, including pre-conditioning and full sterilization time
- **Containers stored on an open rack in the same hallway as the drying cabinets**



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Process Differences

- **Timing**
  - Turnaround time similar for sterilization and automated HLD
  - 10 minutes of drying time after cleaning instead of after HLD
    - Automated drying cabinets remove the scope tech time
  - 2 cycle abortions (moisture in the scope, failure to follow the IFU) similar to AER
- **Physical space**
  - Footprint of the sterilizer (capable of processing 1 scope) was just a little bit smaller than AER (fits 2 scopes)
  - Heat produced by the sterilizer was felt to be notably more than an AER
  - Storage of rigid containers similar footprints to the current drying cabinets
  - Cleaning/disinfection of rigid containers similar in process and space to cleaning of trays used to transport the scopes from the current drying cabinet
    - Cart washer to complete this work would be ideal.
  - Forced air for drying on decontam, not clean side

Process Differences

- **Cost**
  - Capital purchase of the sterilization equipment
  - Single-use connectors between the container and the scope
    - Scopes require 4-8 of these connectors based on lumens and other factors
  - Rigid containers purchase and maintenance

- **Additional Advantages**
  - No need for routine re-processing un-used scope
    - 6-month expiration of sterility
  - AERs have large requirements for plumbing, drainage and water quality assurance through filter maintenance; none of these items would be necessary for sterilization.

Survey Results

- **Likert scale of 1 (strongly disagree) to 5 (strongly agree)**

User's Guide	4.8
Connector assembly Process	5.0
Sterilizer process	4.6
SteroScope® Overall Rating	4.7

- **Selected Comments**
  - User friendly
  - Easy to learn
  - Handouts with instructions and pictures would be helpful

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Conclusion

- **Observations**
  - Didn’t trial process to take sterilization containers to procedure rooms
  - Unable to assess retention of training
  - This endoscopy center has a relatively high-end set-up, with AERs and forced-air drying cabinets
    - A center with different HLD and drying modalities may have more impact to workload and physical space

- **Overall, it was a success study as far as learnings and acceptability**
  - Sense of pride for participation by our team!

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