Clean Scopes, Safe Patients: Infection Control in Today's Endoscopy

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Presenter Disclosure

Dyan Darga is an employee of Healthmark Industries, a Getinge company, a manufacturer and distributor of medical products.

No compensation has been received for this presentation.

All opinions are those of the presenter.

This presentation is for information only, not for training or promotion. Always read the device instructions and safety information before use.

Questions for you and for me

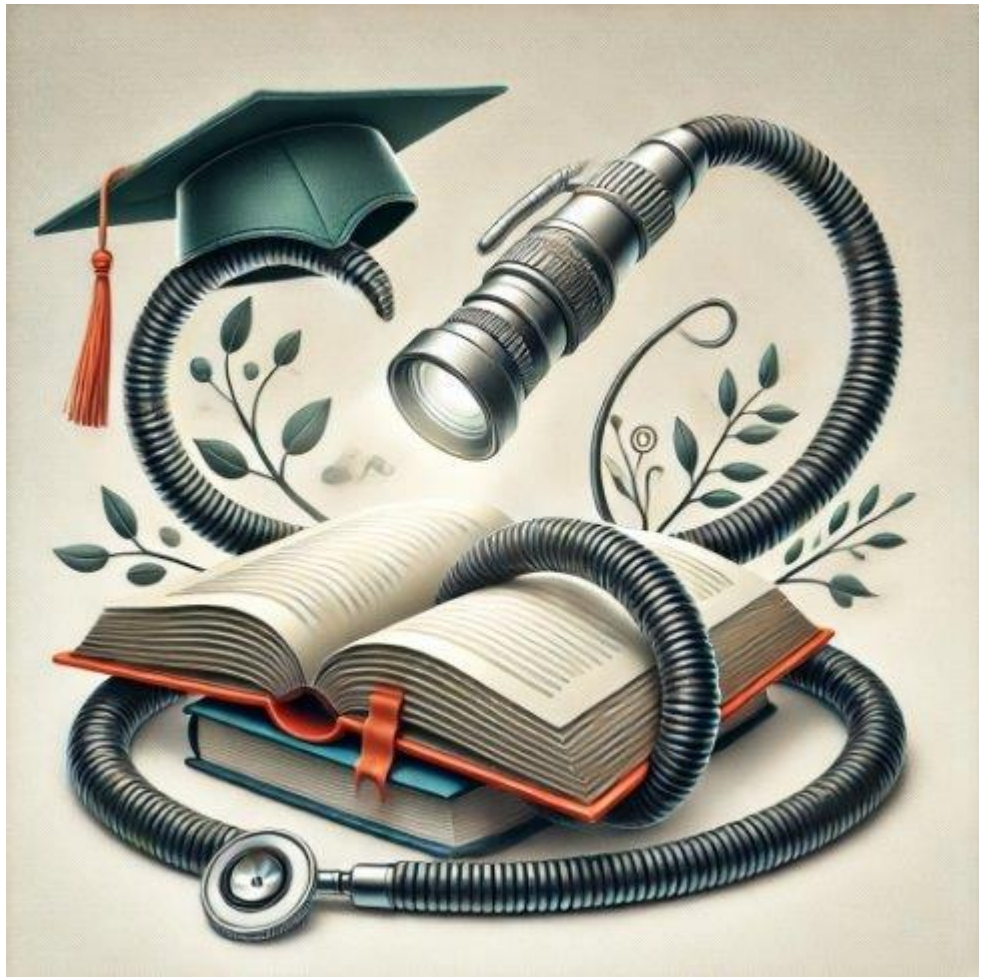
1. How many of you feel relatively well-versed with endoscopy reprocessing?

2. Show of hands, years of experience in IP – 0-2, 3-5, 6-10, 10+ ?

3. Feel free to raise your hand to ask questions during the presentation.

4. Stop me if I use an acronym you are not familiar with.

I am here for YOU and want to be sure you understand what I am trying to convey.



Learning Objectives

- Discuss the **infection risks** associated with endoscopy procedures
- Explain the **vital role of Infection Preventionists**, as part of a multidisciplinary team, to drive compliance for safe endoscopic reprocessing practices
- **Review each step** of the scope reprocessing cycle, **highlighting key points** to observe for during practice reviews/audits
- Review some **hot topics** in endoscopy and how they relate to infection prevention

Review of 2 Recent Outbreaks

Published April 2025

Timeline of Endoscope-related Outbreak

OXA-181 Carbapanemase producing *K. Pneumonia*-- in Mecklenburg, Germany

Nineteen pts infected -16 of the 19 - (84%) had recently undergone at least one **GI procedure**. Primary **investigation** of endoscopes **found no irregularities**

July 2022

Outbreak prompted systematic inspection of all scopes

August 2022

Outbreak strain was isolated from a ready to use endoscope

September 2022

All scopes exceeding 10 years, were disposed of, and new ones purchased

October 2022

Strain was again noted in a new scope that had been reprocessed according to MIFU's using an AEWD

February 2023

An **additional 13 patients were identified as being colonized or infected** with the outbreak strain (discovered primarily due to hospital wide screening)

March 2023

After **aggressive training, audits, cleaning, and strict isolation measures** – Outbreak ended

Haak, J., Klempien, I., Hans, J., Schaefer, S., Meyer-Bothling, K., Gatermann, S., Dirks, E., Konrat, K., & Arvand, M. (2025). Endoscope-associated outbreak of oxa-181-carbapenemase-producing klebsiella pneumoniae and its implications for hygiene management. *Journal of Hospital Infection*, *158*, 19–28. https://doi.org/10.1016/j.jhin.2025.01.016

OXA-181 Carbapanemase producing *K. Pneumonia*-- in Mecklenburg, Germany

Outbreak Discussion:

- Multiple audits found **no reprocessing breaches**, confirmed full compliance with guidelines and IFU's
- They found **residual moisture in channels** despite being stored in a drying cabinet & **biofilm** formation was thought to be a key factor contributing to this outbreak.
- They found that this strain had developed a **tolerance to peracetic acid**
- For patients with known infection/colonization – **intensified processing** was performed w**/ double concentrated PAA and double contact time**
- Intensified IPC measures **(isolation, dedicated staff for pts., improved cleaning/monitoring**) helped end the outbreak – **These measures are still in place.**
- A **total of 32 patients** were assigned the outbreak, **13 of whom suffered infections** and 19 of whom were colonized.
- **Six patients died**, 3 of whom had the *K. Pneumoniae* diagnosis as **the most likely cause of death**.

2024 Outbreak Investigation of NDM producing *E. Coli* at a large teaching hospital in Detroit, MI

- Used Whole Genomic sequencing program (WGS) to isolate
- New Delhi metallo-B-lactamase (NDM) producing *E. coli (MDR)*

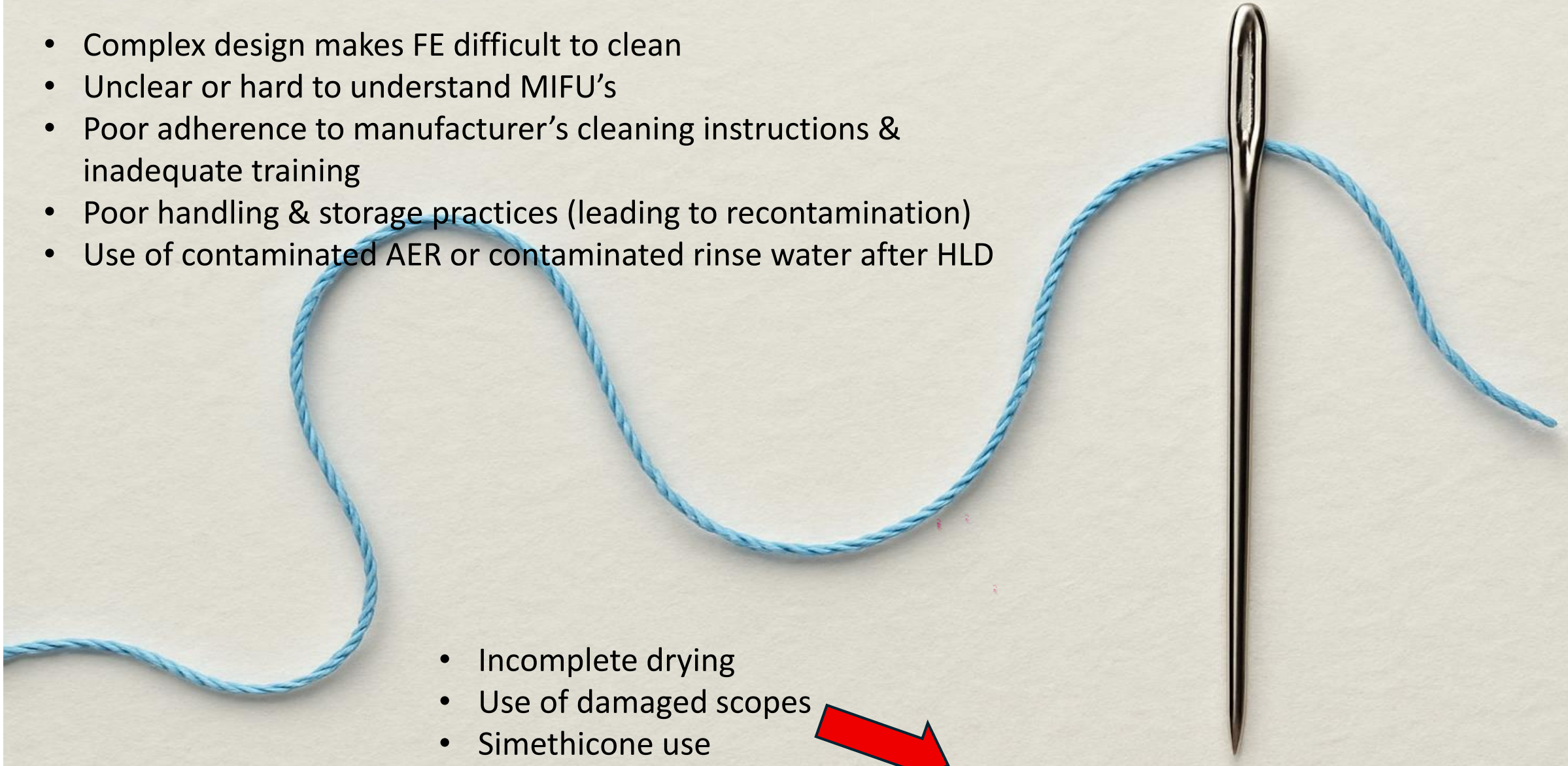
- 9 patients identified and 8 of them had recently undergone ERCP and/or EGD
- 6 patients had clinical infection and 3 were colonized
- WGS investigation linked the scopes to infections
- 3 patients died, but only 1 death was related to NDM infection

- **Guess how many days (on average) it took for patients to show symptoms after exposure?**

- No reprocessing breaches were identified
- Expanded protein testing to all channeled endoscopes
- All implicated scopes removed from service
- Changed to Duodenoscopes with disposable end caps

Common Threads in processing that **increase infection risks**

- Complex design makes FE difficult to clean
- Unclear or hard to understand MIFU's
- Poor adherence to manufacturer's cleaning instructions & inadequate training
- Poor handling & storage practices (leading to recontamination)
- Use of contaminated AER or contaminated rinse water after HLD



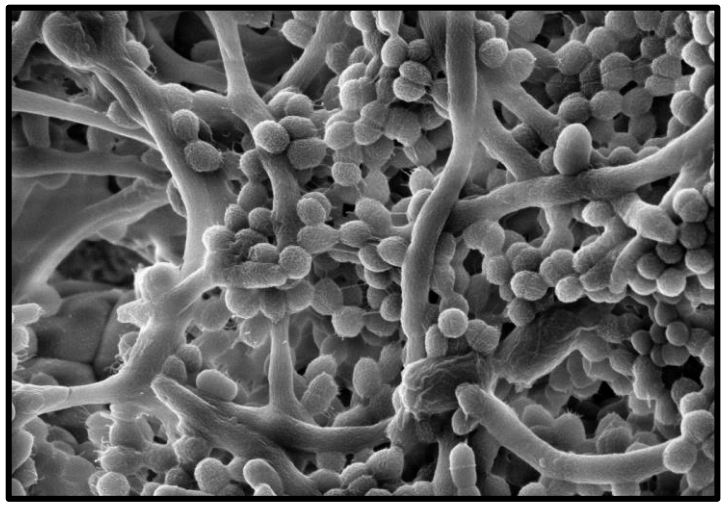
- Incomplete drying
- Use of damaged scopes
- Simethicone use
- Delayed reprocessing

BIOFILM FORMATION

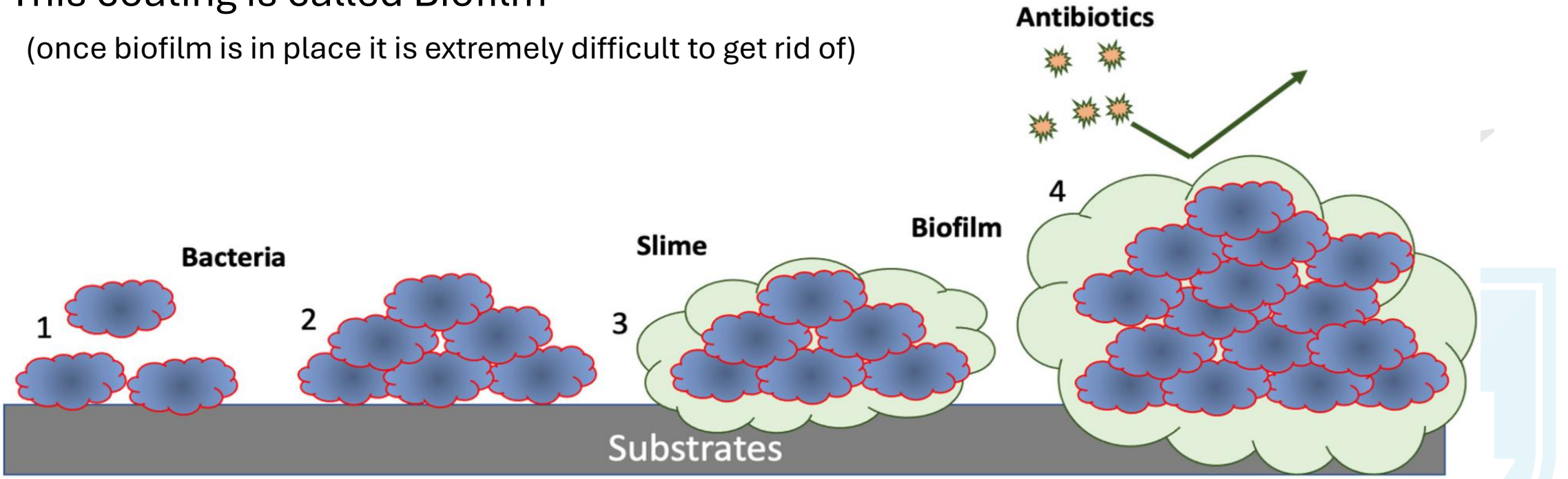
How Biofilm forms:

1. Bacteria attach to a surface
2. They multiply
3. They produce a slimy, sticky coating that helps them stay put and protect themselves
4. This coating is called Biofilm

   (once biofilm is in place it is extremely difficult to get rid of)



https://www.igb.fraunhofer.de/en/research/biofilms-and-hygiene/



https://www.mdpi.com/applmicrobiol/applmicrobiol-03-00044/article_deploy/html/images/applmicrobiol-03-00044-g001-550.jpg

FACT: More healthcare-associated infections are linked to contaminated endoscopes than any other device!!!

Many studies from multiple countries have documented a failure to comply w/ proper HLD processes → Process problem?

Infections are occurring even when all processing steps are followed according to MIFU's. → Complex device design

Recent studies have shown that 15–20% of patient ready endoscopes harbor bacteria → Patient Infections

Long latency period between initial exposure and s/s of infection make it difficult to trace the infections back to contaminated endoscopes → Underreporting

(Kenters, et al 2015; Rutala, et al 2019)

How prevalent are infections related to endoscopic procedures?

Historically have been **radically underestimated** or based **on inaccurate figures**

Continues to be characterized as **“extremely rare”** (<1/1 million) without any substantiating evidence

Many outbreaks are only detected because **MDRO’s attract the attention of IP’s** and are followed up on

Ofstead, C. L., Buro, B. L., Hopkins, K. M., Eiland, J. E., Wetzler, H. P., & Lichtenstein, D. R. (2020). Duodenoscope-associated infection prevention: A call for evidence-based decision making. *Endoscopy International Open*, *08*(12), E1769–E1781. https://doi.org/10.1055/a-1264-7173

Reasons for Underestimation of Risk & Underreporting

- Scarcity of prospective studies
- Inability to trace infections when pts go to primary care or GI physician's office *
- Failure to detect asymptomatic colonization due to lack of routine screening (infection is dormant)
- Long lag times between procedures and appearance of infection
- Infections in areas of the body not typically associated with GI procedures (urinary tract, lungs, blood stream)
- Transmission of bacteria that are typically endogenous gut flora and are assumed to have originated from the patient rather than a device
- Some known outbreaks have not been published nor used for risk estimates

Retrospective studies show a very different picture

- Data calculated from 15 duodenoscope-related outbreaks showed the lowest rate to be 6% and 9 of the 15 had rates from 14% - 41%
- Even for scopes without elevators, post procedure infections are not “very rare” (<1/10,000) or even “rare”(<1/1000)

- New genetic and molecular tests (WGS) now allow the detection of outbreak organisms and can directly link them to contaminated endoscopes

We are only seeing the Tip of the Iceberg

Ofstead, C. L., Buro, B. L., Hopkins, K. M., Eiland, J. E., Wetzler, H. P., & Lichtenstein, D. R. (2020). Duodenoscope-associated infection prevention: A call for evidence-based decision making. *Endoscopy International Open*, *08*(12), E1769–E1781. https://doi.org/10.1055/a-1264-7173

Johns Hopkins Study on Incidence of Post-Endoscopic Infections in ASC's

- Over 15 million colonoscopies and 7 million EGD are performed annually in the U.S.
- Over 50% of endoscopic procedures are now performed in ASC's in the U.S.

Retrospective look at approximately 31% of the US population in ASCs over 7 days

Information retrieved from all-payer claims data from 6 states.

Compared infection rates against those of screening mammo's, prostate CA screening, bronchs, & cystos

Tracked infection related ED visits and unplanned inpatient readmissions within 7 and 30 days.

1 Wang P, et al. Rates of infection after colonoscopy and osophagogastroduodenoscopy in ambulatory surgery centres in the USA. Gut. 2018 Sep;67(9):1626-1636.

Johns Hopkins Study on Incidence of Post-Endoscopic Infections in ASC's

30-Day Endoscopy Caused HAIs	
Procedure	**Readmissions due to Infection**
Screening Colonoscopy	**1/250**
Non-Screening Colonoscopy	**1/185**
EGD	**1/91**

Interesting to note:

- Invasiveness (polypectomy, etc) did not alter the infection risk
- Type of Anesthesia (General vs. MAC or Mod Sed) had no impact on infection rates
- ASC's with higher procedure volume had the lowest rates of post endoscopic infections

Conclusion: "We found that post-endoscopic infections are more common than previously thought…and are occurring without being detected by existing surveillance systems."

1 Wang P, et al. Rates of infection after colonoscopy and osophagogastroduodenoscopy in ambulatory surgery centres in the USA. Gut. 2018 Sep;67(9):1626-1636.

Why IPs are vital to preventing endoscopy associated infections

1. **Infection Risk Mitigation:** develop and enforce protocols to prevent HAI's
2. **Device Reprocessing Oversight:** IP's ensure best practices and regulatory guidelines are being followed
3. **Compliance with Standards:** IP's help facilities adhere to the standards set by guiding organizations
4. **Education/Training:** IP's provide ongoing training for staff on aseptic technique, updated IP guidelines
5. **Surveillance/ Monitoring:** IP's conduct routine monitoring departmental practices to ensure continuous quality improvement
6. **Policy Development:** IP's are part of the multi-disciplinary team that create and refine IP policies
7. **Advocate for patient safety** by reducing infection risks for patients
8. **Emerging Risks:** IP's are often the first to know about new infectious threats or challenges and adapt protocols to mitigate them
9. **Cross-Department Collaboration**: to ensure a unified approach to Infection prevention.

Endoscope Processing Guidance

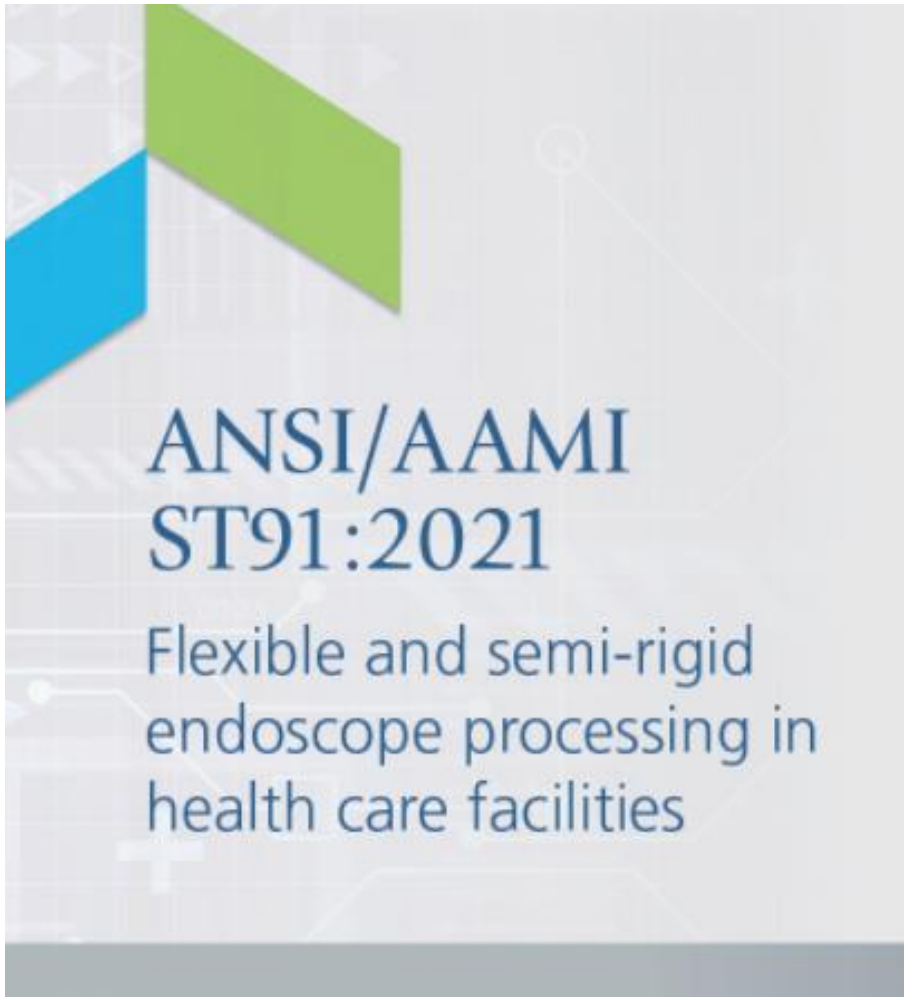
LET'S JUMP IN!

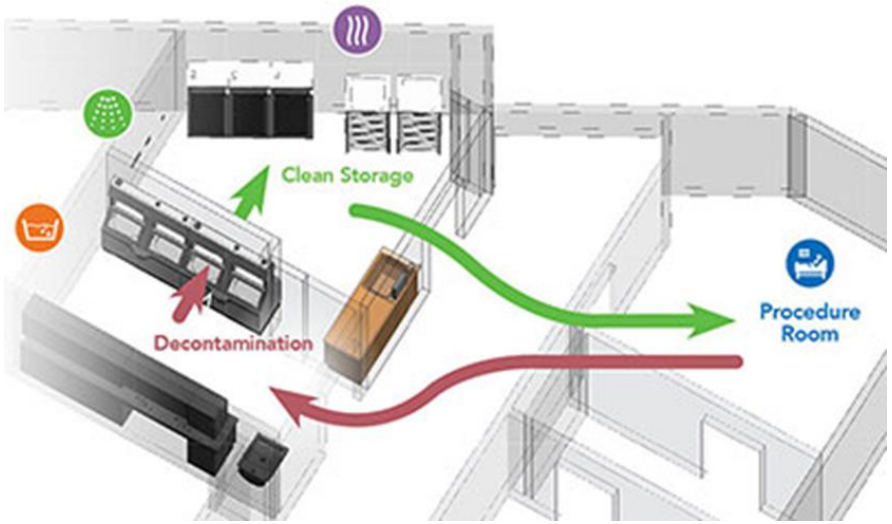
AAMI = Association for the Advancement of Medical Instrumentation

ANSI/AAMI ST91: 2021

Released 3/3/22

- Contains best practices for endoscope reprocessing in ANY setting
- Excludes TEE/ultrasound probes
- Inclusion of peer-reviewed research and FDA MAUDE database citations
- Replaces 2015 standard





https://www.steris.com/healthcare/knowledge-center/sterile-processing/endoscopy-reprocessing-standards

ST91 General Considerations

1. Physical Space Design:

- Strict unidirectional workflow and preferred 2-room design
- If not 2 rooms, minimum 4 feet of separation between decontam and clean work area with a wall or barrier separation.

2. New High-risk scope category

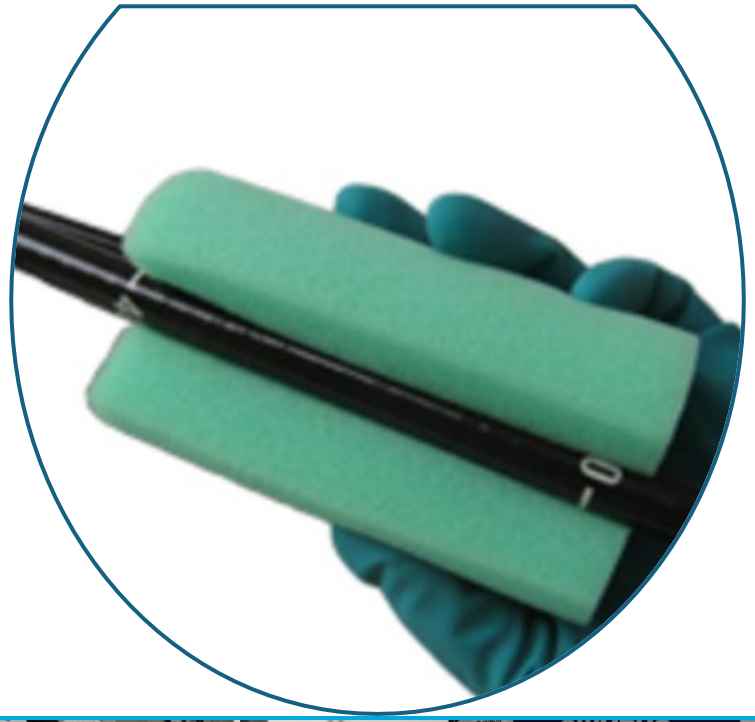
- Associated with infections and difficult to reprocess
- Duodenoscopes, linear ultrasound (EUS) endoscopes, bronchoscopes, endobronchial ultrasound (EBUS) endoscopes, ureteroscopes, cystoscopes, and as determined by the facility
- Cleaning verification required for these scopes

3. Certification for processing staff

- Recommend Certification for all processing staff after 2 years of experience in the field.

Point of Use Treatment

Formerly “bedside clean” or “pre-clean”



- Initial removal of soil to decrease bioburden load for subsequent steps
- Timing crucial – need to limit bioburden before it dries

WHY?

To reflect everything done at point of use – including precleaning but also:

- Disconnecting accessories
- Preparation for transport
- Preparing **handoff communication**

POU tx – Handoff Communication

"Golden Hour" - Olympus calls for **extended detergent soaking** if there is **more than a one-hour delay** between POU tx and manual cleaning.

- Processing personnel need to know how long the endoscope has been awaiting processing –
  - To establish priority order
  - To determine whether delayed reprocessing protocol is needed
  - NEED A METHOD FOR CONVEYING THE PRECLEANING TIME TO PROCESSING STAFF
- Include Pt. ID, date/time of procedure, name of person performing POU tx.

Soiled transport

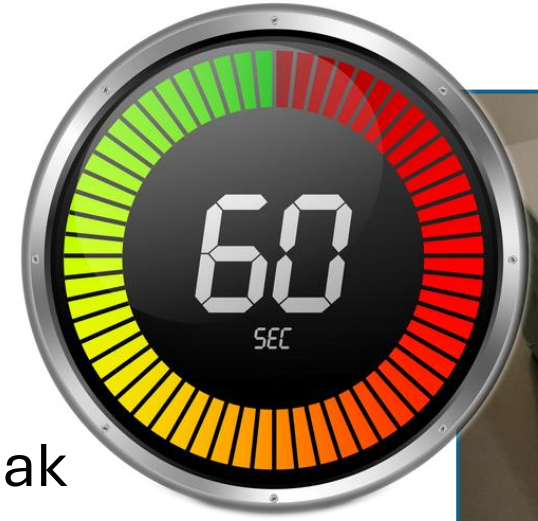
- Scopes kept moist for transport
- Transport container or cart:
  - Nonporous
  - Leak-proof on sides and bottom
  - Puncture-resistant
  - Labeled as biohazard
- Delayed processing protocol reinforced - Olympus
- Lasagna

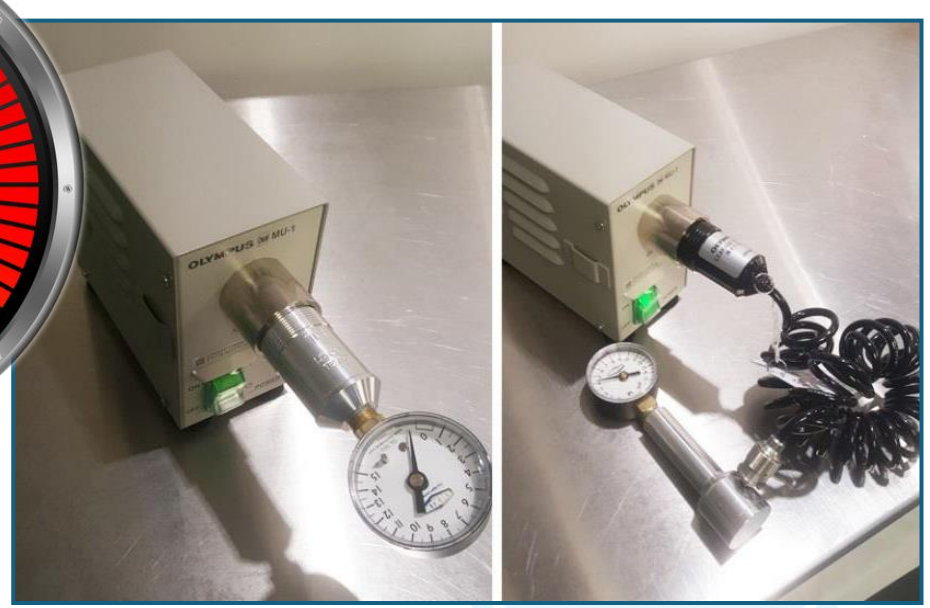
Leak Testing

Why?

How often?

- Flush all channels with water to remove trapped air with a new syringe
- Manipulate knobs, buttons, elevator
- Documentation of testing
- When a leak is discovered –
  - Follow endoscope manufacturer IFUs for processing
  - Tag the scope-”Do not use”
  - Remove from use
- Daily QA for automated and manual leak testers of output validation (LTT)





Cleaning

Manual

Most important part of process, removes 99.9% of bioburden

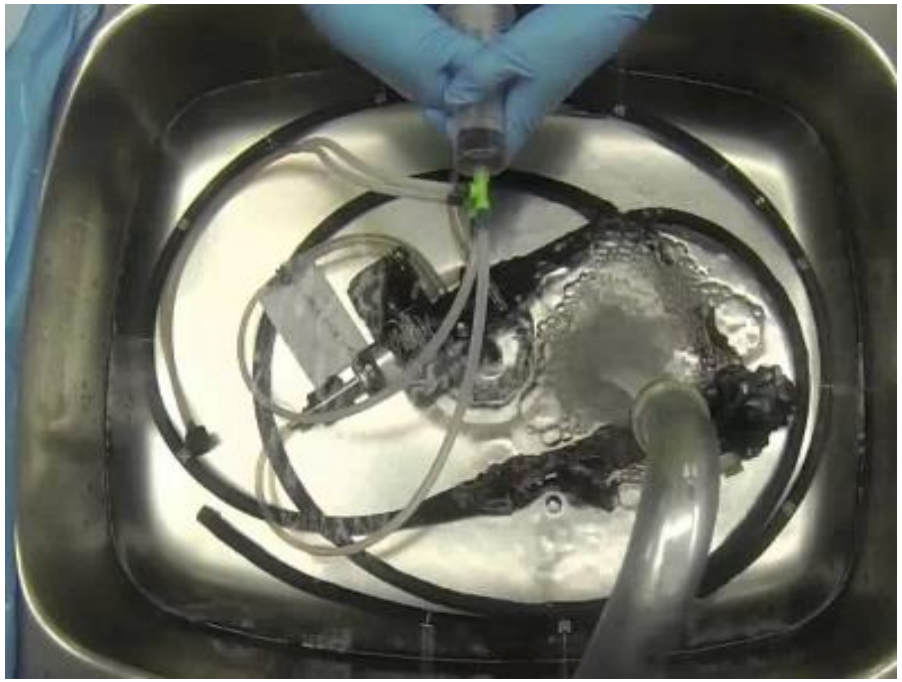
Utility water rinse

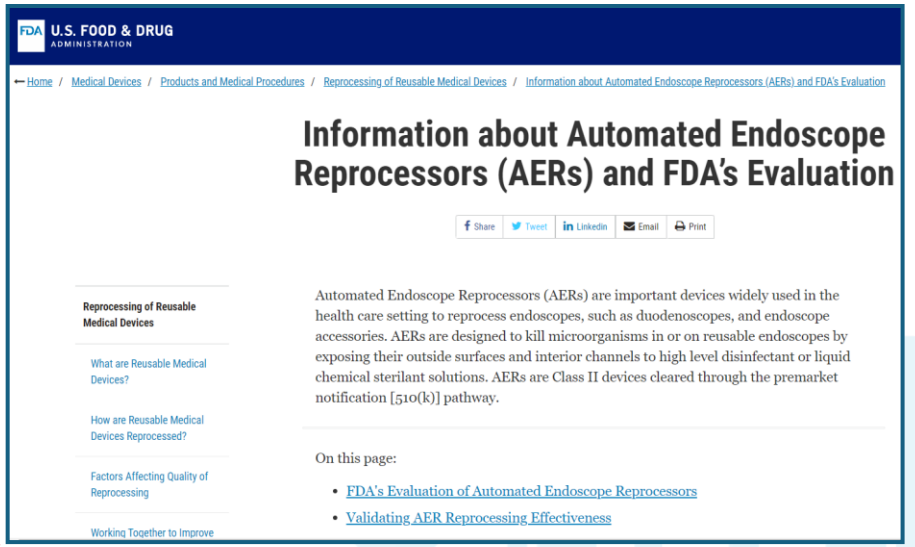
Drying – exterior and channels

Automated

Cleaning cycle vs. Cleaning claim

Reinforces FDA direction re: **duodenoscopes (ie. regardless what kind AER, must manually clean at sink)**





https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/information-about-automated-endoscope-reprocessors-aers-and-fdas-evaluation

Enhanced Visual Inspection

Basic visual inspection with unaided eye – is now a **minimum** standard

Enhanced visual inspection is a strong recommendation in ST 91 and includes:

- Lighted magnification
- 5X, 10X
- Cleanliness, missing parts, lens integrity, seals/gaskets

https://www.google.com/url?sa=i&url=https%3A%2F%2Fwww.mobileaspects.com%2Fthe-importance-of-visual-inspection-for-endoscope-reprocessing%2

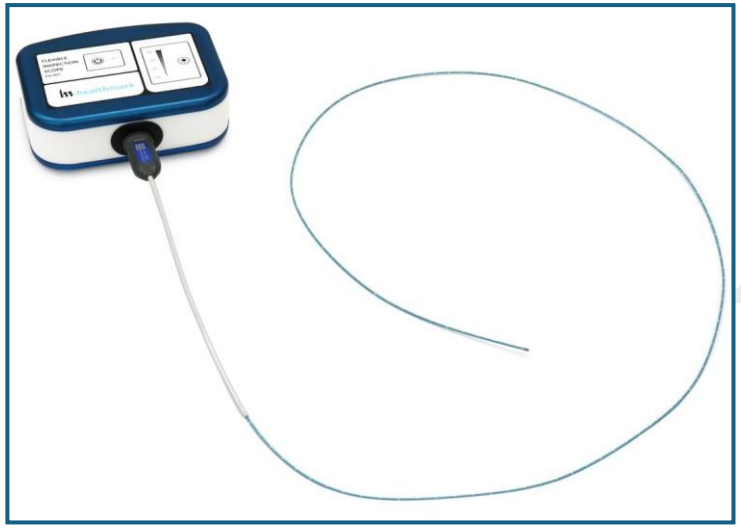
Cleaning Verification & Borescope Use

Cleaning verification –w/rapid cleaning monitors

- Multiple ways of accomplishing this (test strips or ATP)
- “High-risk endoscopes” after each use
- Repeated failures – send scope for evaluation/repair

Borescopic inspection -

- Channels, distal tip, valve openings
- Follow endoscope MIFUs for what to inspect



https://www.google.com/url?sa=i&url=https%3A%2F%2Fwww.mobileaspects.com%2Fthe-importance-of-visual-inspection-for-endoscope-reprocessing%2

High-Level Disinfection

- HLD is the minimum level of processing for **semi-critical** endoscopes and kills everything but some bacterial spores
- Manual HLD (soaking in a bin) is not recommended and should only be used as a last resort
- If scope goes into procedure room and not used, must be re-HLD'd
- If scope sits in AER after cycle for > 1 hour, needs to be re-processed
- "All flexible endoscopes that are introduced directly into the bloodstream or that contact a normally sterile tissue or body space during use are considered **critical devices** and should be sterilized"

Sterilization Options

Liquid Chemical Sterilization

- a method used to disinfect heat-sensitive devices
- immersing the device in a liquid chemical sterilant for a specific length of time to eliminate all microorganisms, including spores

Challenges:

- With LCS, the devices are not wrapped and therefore there is no way to maintain sterility after processing
- Hung in cabinets like HLD'd scopes
- If using in a sterile capacity, must be sterilized immediately prior to use

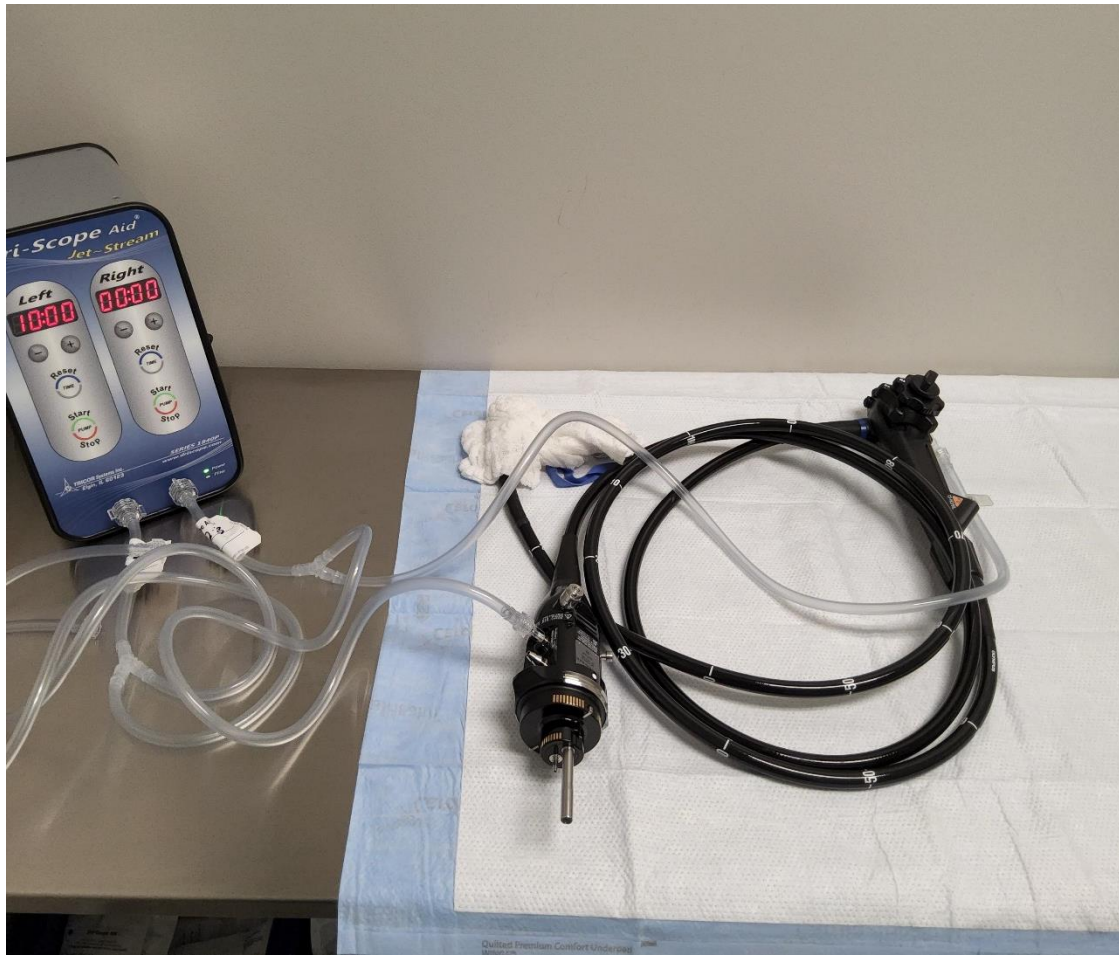
Terminal Sterilization

- Preferred over HLD and LCS for FE processing and sterilization is the **only option** for instruments used in critical uses entering the bloodstream or sterile areas
- Scopes are sterilized in trays, wrapped, and stored in sterile areas. Can be used as long as the integrity of the wrap/container is good. No hang time considerations

- Three methods:
  - Ethylene Oxide (EO) –
  - Hydrogen Peroxide gas w/wo plasma-
  - Hydrogen Peroxide Ozone

Drying

- Need to dry scopes prior to storage or reuse **Never** store wet
- Bacteria 70% water; need it to live
- Exponential growth if not eliminated → biofilm formation
- Eliminate the water → bacteria can't survive
- Use non-linting, lint free, or sterile cloth
- AER purge cycle ≠ drying
- **Minimum of 10-minutes with pressure-regulated forced instrument/HEPA filtered air**



Drying

- PSI considerations – 25 psi is OK for most scopes

- Forced air nozzles are not recommended and if used, should be cleaned between uses*
  - PSI may be regulated, but typically at much higher levels – 72psi should be max for large channeled scopes

- Avoid intermingling scopes drying post HLD with scopes drying prior to sterilization

Air Blowgun Hose

Clean Handling/Transport

- Hand hygiene and clean gloves when handling
- Horizontal transport in container
- Should be identifiable as “patient ready” or clean
- Do not do this

Storage

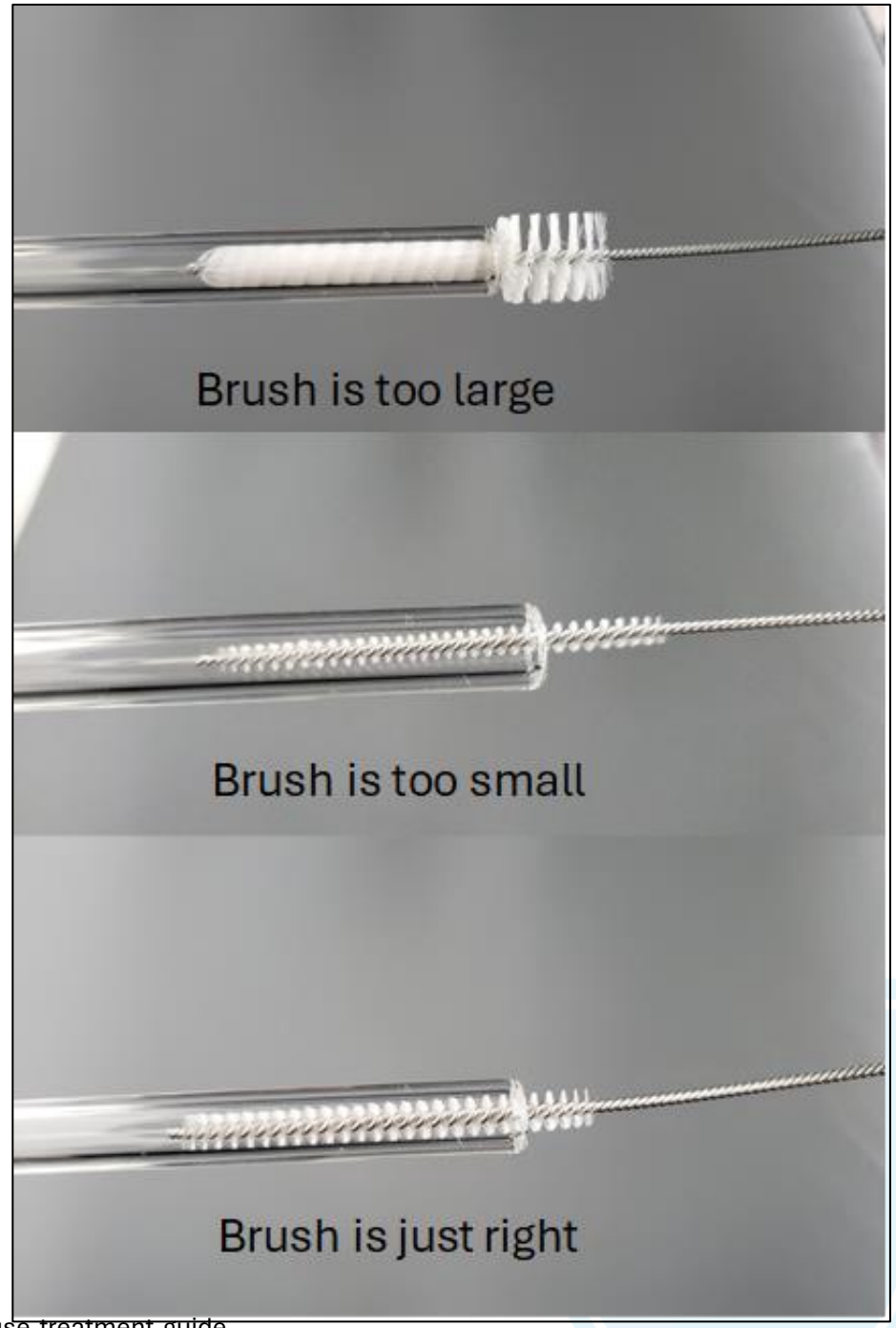
- Cabinets: protect from contamination & damage
  - PREFERRED - drying cabinets-internal channels
  - AT A MINIMUM - conventional cabinets with **HEPA-filtered air circulating**
- No endoscope storage in procedure room or processing room
- Keep valves together with the endoscope as a unique set

- Clean cabinets at least weekly
- Visual cues on patient ready scope
- Multidisciplinary risk assessment re: **“hang time”**

https://www.medivators.com/products/endoscope-reprocessing/endoscope-transport-and-storage/endodry-storage-and-drying-system

Top 7 Mistakes Made in Manual Cleaning

1. **Skipping the point of use treatment**
2. **Inadequate leak test**
3. Incorrect brush size for lumen or not brushing all channels
4. **Delayed reprocessing (>1hr)**
5. **Insufficient drying**
6. **Improper handling and storage**
7. Neglecting visual inspection



https://www.steris.com/healthcare/knowledge-center/sterile-processing/endoscope-manual-cleaning-and-point-of-use-treatment-guide

APIC, 2025

Comparison table of Endoscope Standards and Guidelines

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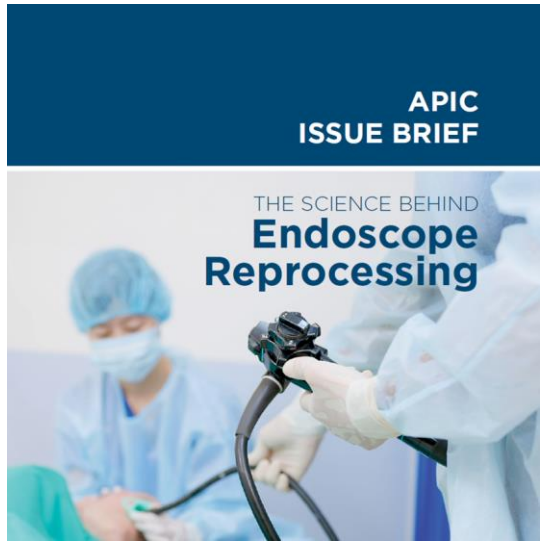


https://apic.org/wp-content/uploads/2025/03/2025-APIC-Endoscope-Issue-Brief.pdf

Comparison Table of Endoscope Standards and Guidelines

	CLEANING	INSPECTION	HLD	STERILIZATION	DRYING	STORAGE	HANG TIME	TRANSPORT
AAMI ST91:2021[1]	Should be initiated within 1 hour; Begins at the POU Suction cleaning solution through instrument/suction channel and flush air, water, and other channels.	Can include a borescope, and should occur after manual cleaning in a well-lit area; Lighted magnification should be used, specifically 5x for endoscope, 10x for duodenoscope; Cleaning verification for high-risk endoscopes.	Manual processing is not recommended, an AER is preferred.	Preferred method of microbial inactivation; Recommended for endoscopes that are high-risk; Manual LCS is not recommended.	Dry internal channels for 10 minutes and outside with lint-free cloth; Use HEPA air through channels for the time recommended by IFU; 70-90% ethyl or isopropyl alcohol may facilitate drying but should conduct a risk assessment.	Endoscopes should not be stored wet; Active drying or a cabinet that circulates air is preferred.	Recommends risk assessment since not well defined.	Clean, covered, solid, leak-proof container; Not coiled.
AORN[5]	Manual cleaning to begin within 1 hour from POU.	Lighted magnification at least 10x; Use a borescope prior to HLD or sterilization.	Use automated processing for HLD or LCS.	Sterilize when manufacturers have validated, if possible.	Dry using instrument or HEPA-filtered air for a minimum of 10 minutes; Dry exterior with lint-free cloth.	Secure location not in the endoscopy suite; Ventilated or drying storage.	Unresolved issue; Mentions 7 days and a risk assessment.	Closed container/cart, leak-proof, puncture-resistant, labeled, and large enough to fit the endoscope.
APIC[2]	Before automated disinfection, precean as soon as the endoscope is removed from the patient in the procedure room; Follow the IFU on the time frame for delayed cleaning; Suction water through channels.	Lighted magnification; May use cleaning verification to confirm the adequacy of cleaning; May use a borescope to detect damage or debris; Reprocess borescope after each use.	Manual process only when an AER is not available.	Consider supplemental measures for duodenoscopes.	With medical grade air and lint-free cloth; Conduct a risk assessment if using 70-90% ethyl or isopropyl alcohol to facilitate drying.	Drying cabinets help to ensure endoscopes remain dry. If drying cabinet not available, storage cabinet should have HEPA-filtered air; Secured area that is not in procedure room; Store in a manner to protect from contamination.	Unresolved issue.	Closed container.
HICPAC[4]	Manual cleaning consistent with IFU; Precean immediately following completion of procedure within the manufacturer's IFU timeframe.	Inspect; May require lighted magnification.	Follow the IFU.	Follow the IFU; Duodenoscopes, unresolved issue.	No mention.	Cabinet to promote drying, prevents recontamination, and protects the equipment from damage.	Perform a risk assessment.	No mention.
Multi-Society Guidelines[20]	Within 1 hour, precean before soil dries; Aspirate detergent through all channels.	Lighted magnification after cleaning and before sterilization.	HLD or LCS in an AER.	Use a technology compatible with the endoscope.	Forced regulated filtered air for 10 minutes; Dry outside with lint-free cloth Follow the IFU for alcohol.	Secured drying or conventional cabinets, Vertical or horizontal.	The facility must determine risks for optimal storage time.	Enclosed, puncture-resistant, leak-proof, and labeled.
SGNA[6]	Recognizes manual cleaning before AER; Within IFU timeframe; Suction cleaning solution through instrument/suction channel and flush air, water, and other channels.	Visual inspection is an essential step; use lighted magnification and adequate lighting. Borescopes may be useful. Choose a method for manual cleaning verification.	Recognized as the standard for reprocessing. Discusses literature that supports a shift from HLD to sterilization but due to cost, process, and time of sterilization, supports efforts for further research on developing standardized, effective processes to improve HLD.	Critical medical devices.	Thoroughly dried before storage is crucial; At least 10 minutes with instrument air; Flush with 70–90% ethyl or isopropyl.	Horizontal storage; no consensus on the type of storage.	Supports 7 days.	Closed, puncture resistant, large enough to prevent damage.

HOT TOPICS in Endoscope Processing

HOT TOPICS in Endoscope Processing

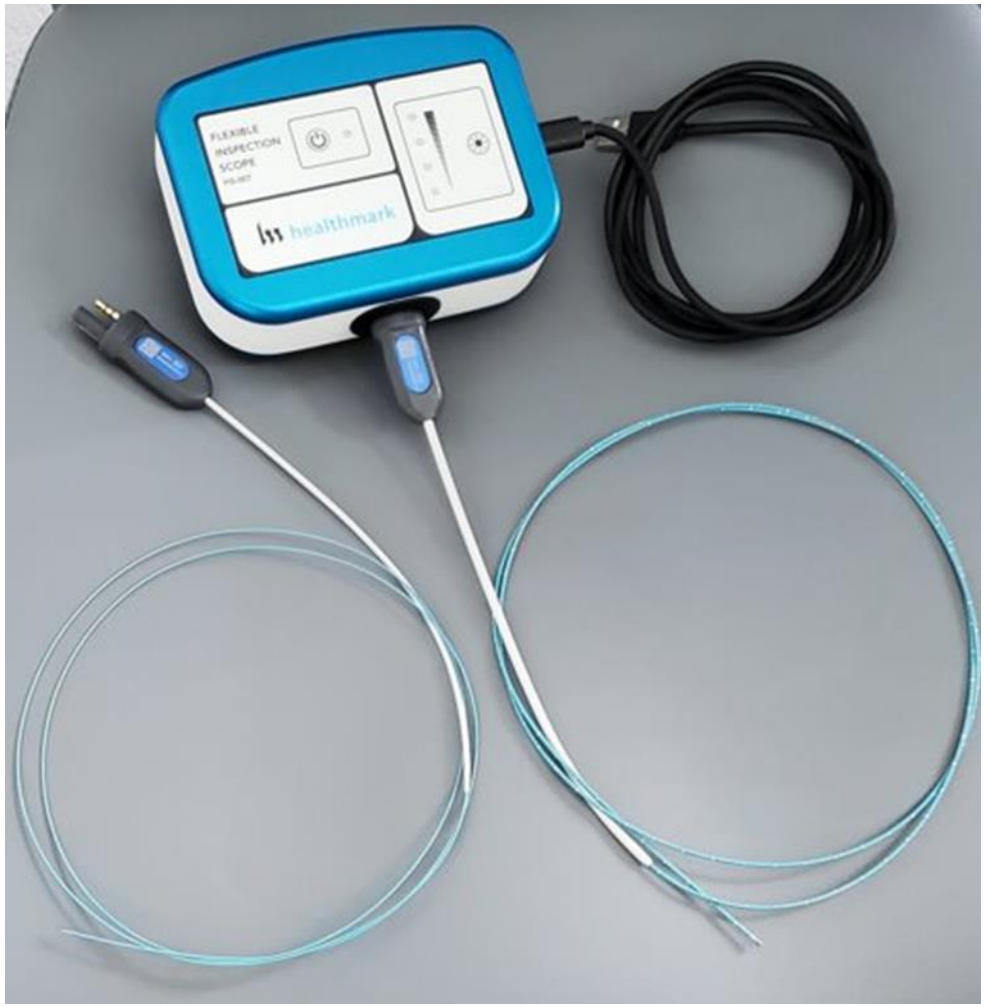
Borescope Use

Simethicone Use

HOT TOPIC

Borescope use

WHAT IS a Borescope Anyways?



Basically – it's a scope that scopes the scope.

Or, in other words, an instrument used to visually inspect the internal channels of endoscopes

WHY SHOULD WE USE a Borescope?

Multiple studies have shown that patient infections have been linked to endoscopes that were damaged or contaminated with visible defects.

2023 Ofstead study looked at 25 endoscopes in an endo dept. and found **visible damage and debris in 100%** of them and 76% required repair.

Scratches and shredding were prevalent, even in scopes that had just returned from repair, and worsened over time. Many of these had intact distal ends which suggests that **visual inspection of external surfaces alone is not sufficient.**

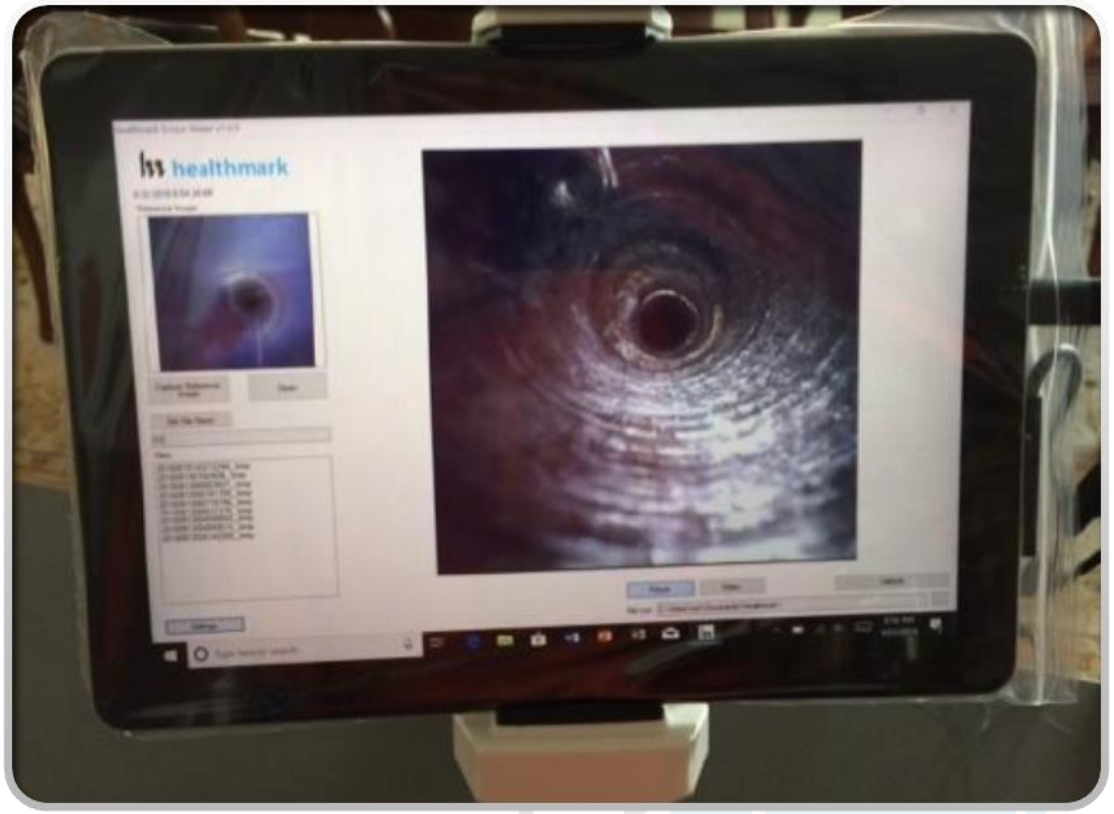
Visual inspection with magnification and borescopes identified actionable defects that could interfere with processing effectiveness in 100% of endoscopes.

WHEN SHOULD WE USE a Borescope?

1. After manual cleaning as part of the visual inspection process

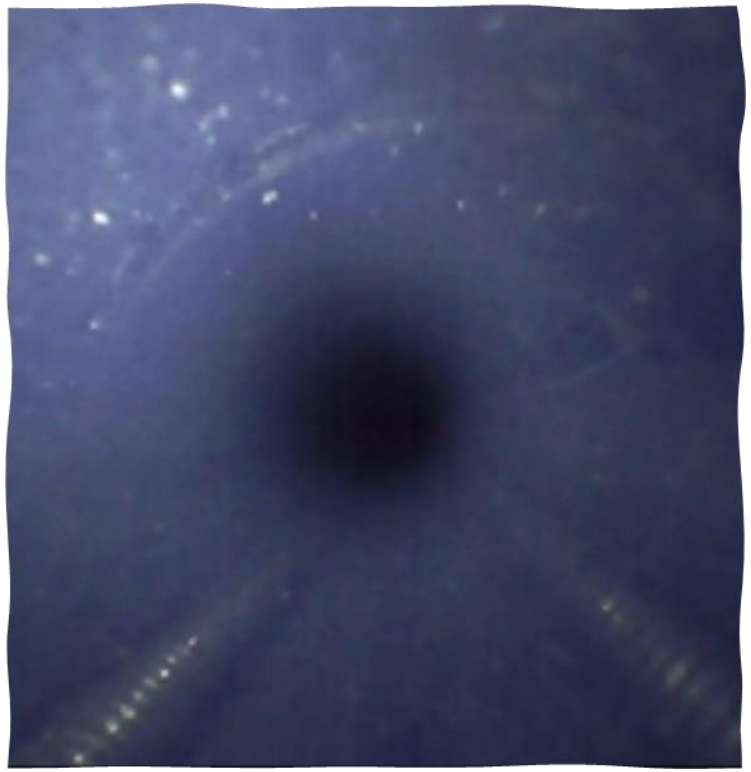
2. When sending scopes out for repair and when receiving them back from repair

3. Can use to assess channel dryness on patient ready endoscopes taken from storage (scope will need to be reprocessed after borescope use – so this is more of a “spot” check).



What are we looking for with a borescope?

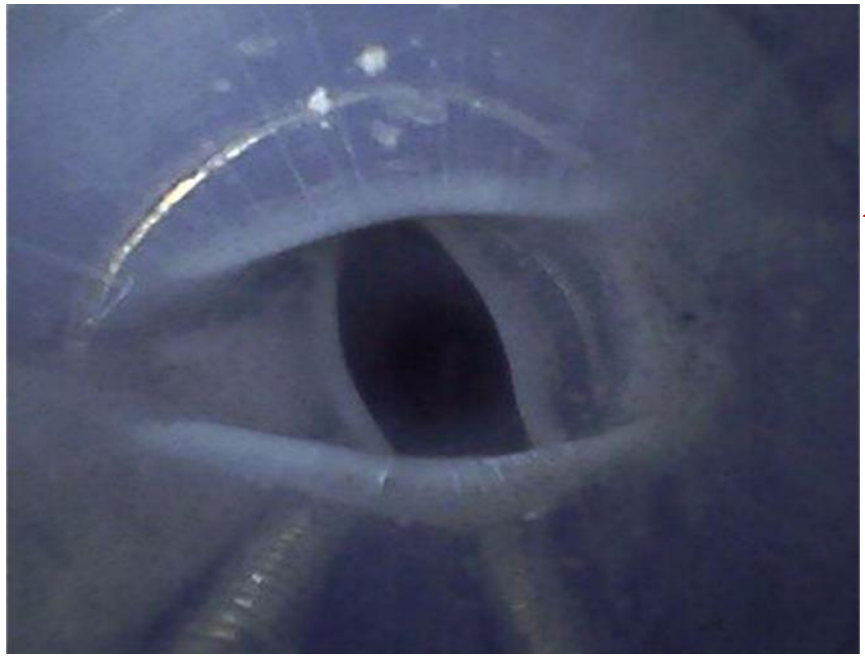
Let's start with what internal channels should look like

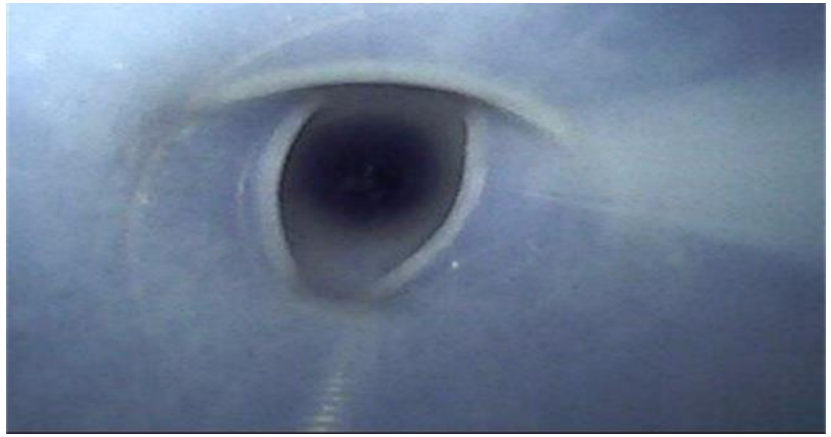


All depictions of normal channels

What Am I Looking At?

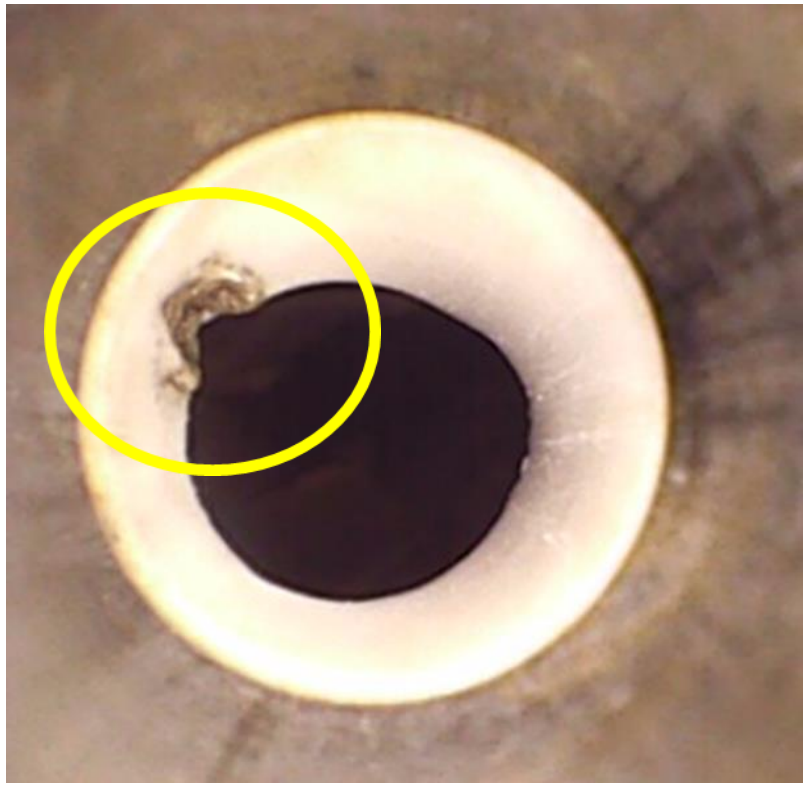
Collapsing Insertion Tube





Ofstead, Cori & Hopkins, Krystina & Eiland, John. (2022). Borescope inspection of endoscope working channels: Why and how?. Endoscopy International Open. 10. E109-E111. 10.1055/a-1512-2813.

What am I looking at?



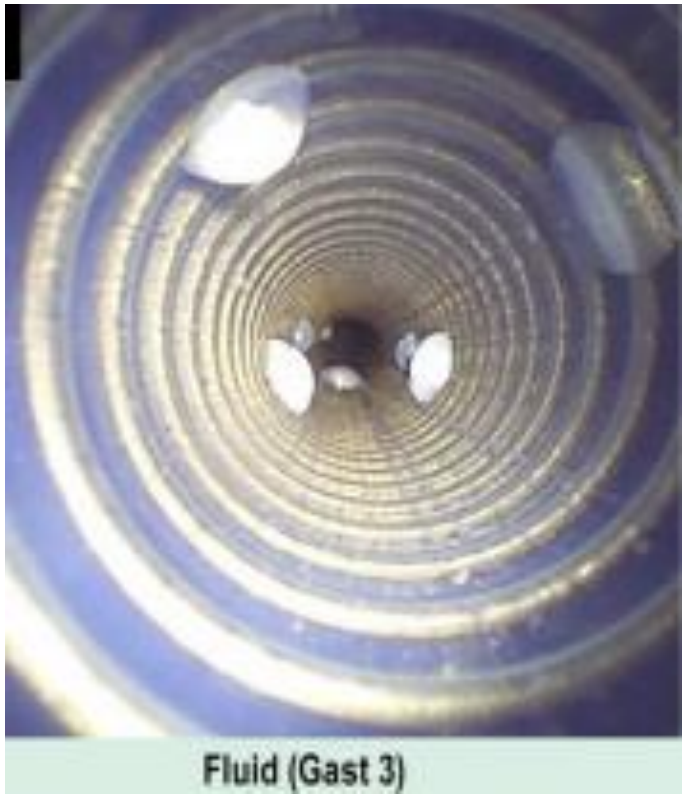
Laser damage

Scratches/peeling Teflon

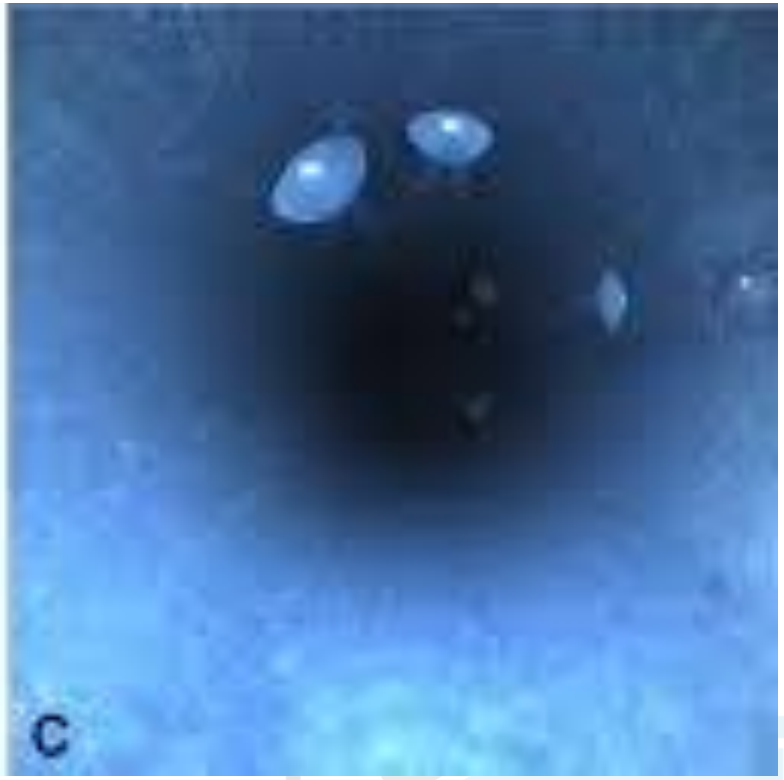
Soil

What am I looking at?

Lint accumulation



Fluid droplets



Simethicone droplets

HOT TOPIC

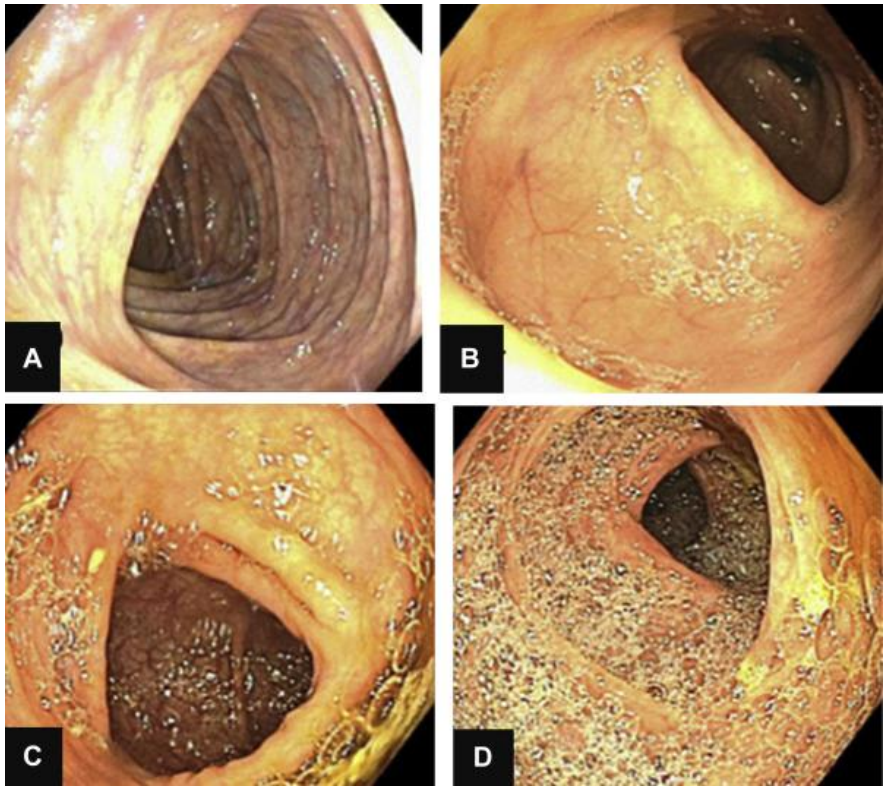
Simethicone Use

How many of you know if Simethicone/Mylicon is used in your endoscopy departments?

Simethicone usage – Background

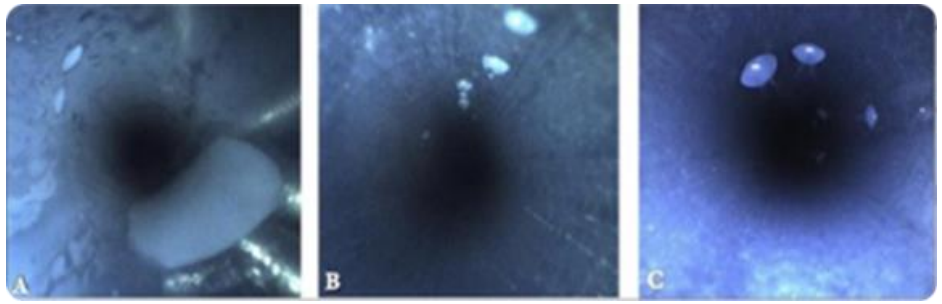
What is simethicone?

- Anti-foaming agent used during endoscopy procedures
- Active ingredient in a variety of OTC anti-gas medications
- Consists of silicone-containing polymers
- Not water soluble
- Has additives such as sugars, flavorings, thickeners
- Studies have demonstrated improved adenoma detection rates with use of simethicone



Kutyla et al., 2018

Simethicone usage – Why is it a Problem?



Multiple studies have demonstrated that simethicone remains in endoscope channels despite repeated cleaning and disinfection procedures, including the water jet

- Interferes with flushing during cleaning, increases risk of bacterial contamination and biofilm development

Sugars and thickeners in formulation can promote microbial growth

Difficult to detect in endoscope channels

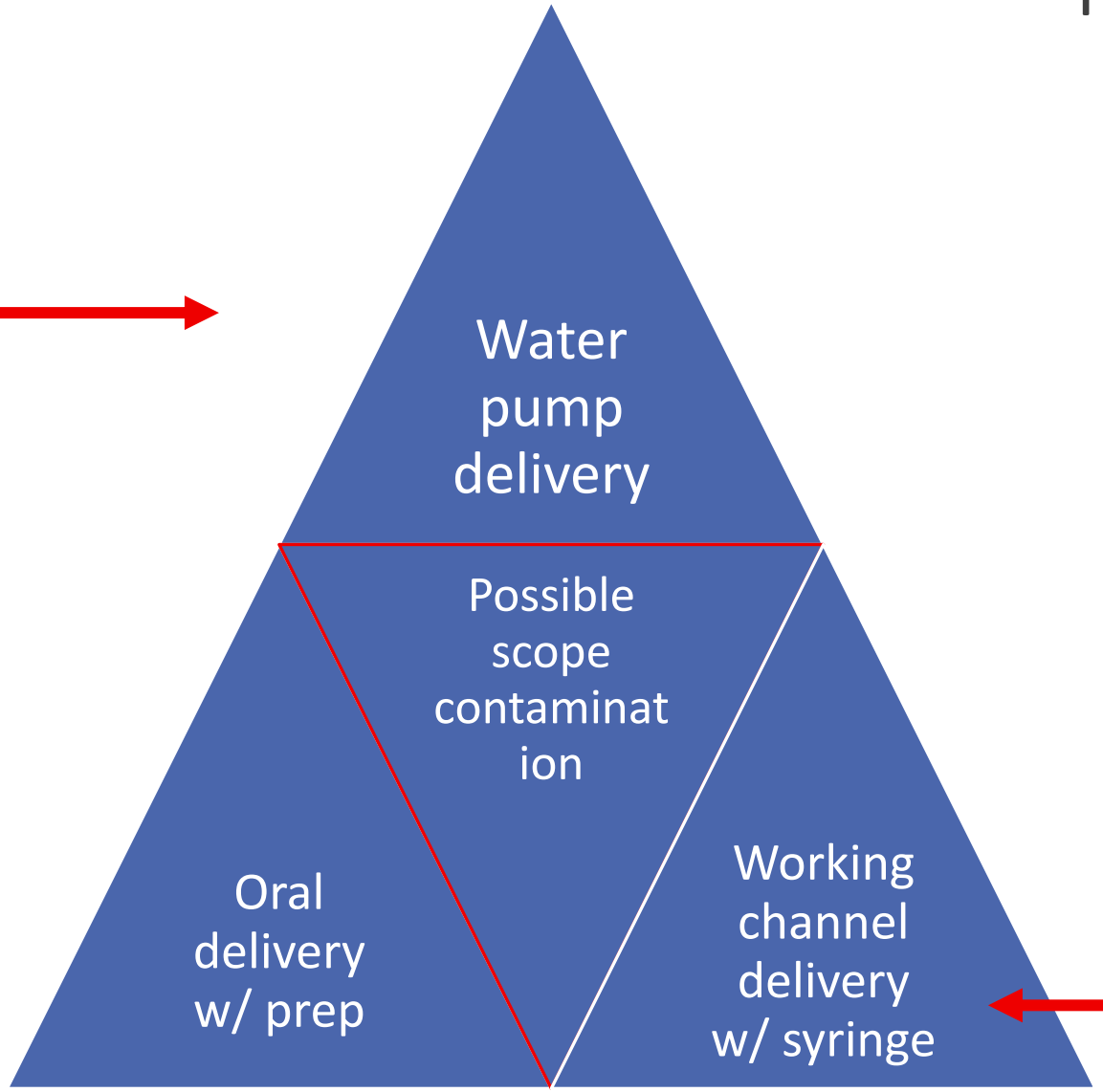
Study demonstrated increased **water droplet retention** when using simethicone

Barakat, 2019

Simethicone Administration Options

Gastroenterologists

- Love it; improves visualization of mucosa
- Inexpensive
- They administer w/ foot pedal
- Fast acting
- May be aware of risk - BUT



- Add into water vessel on top of procedure cart
- Administer w/ syringe via bx port
- May or may not be aware of risk
- May or may not know how to mitigate risk

GI Nurses & Techs

Simethicone Usage Recommendations

AAMI ST91 – Annex G

- Does not recommend the use of simethicone

SGNA:

- Careful use and use lowest concentration possible. Acknowledges that simethicone residue creates an environment that **promotes biofilm formation** and that this can **negatively affect reprocessing efforts**

ASGE:

- Limit simethicone volume and concentration**. Do not use in water jet**, instead use as bowel prep.

Olympus, Fujinon, & Pentax:

- All three Endoscope Manufacturers **recommend against the use of Simthicone**, citing the difficulty of removing it during cleaning as **a risk for endoscope damage** and **potential for contamination that may lead to infections**.

Simethicone: A Call to Action for IP's

69 Fully-Reprocessed Endoscopes at Four Facilities

Observed "cloudy, shimmery fluid resembling simethicone inside channels and under a duodenoscope elevator mechanism"

Microbial cultures were positive in over 50% of samples

Call to Action issued to remove simethicone, insoluble lubricants, and tissue glue from endoscopy labs

American Journal of Infection Control 47 (2019) 666–670

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major Article

Widespread clinical use of simethicone, insoluble lubricants, and tissue glue during endoscopy: A call to action for infection preventionists

Cori L. Ofstead MSPH *, Krystina M. Hopkins MPH, John E. Eiland MS, RN, Harry P. Wetzler MD, MSPH

Ofstead & Associates, Inc, Saint Paul, MN

Key Words:
Endoscope
Silicone
Reprocessing

Background: Current methods for reprocessing flexible endoscopes do not consistently eliminate organic soil. The off-label use of simethicone as a defoaming agent may contribute to reprocessing failures, and endoscope manufacturers have cautioned against its use.

Methods: We sought evidence of simethicone use by interviewing hospital personnel, conducting audits, inspecting endoscopes, and conducting tests.

Results: Researchers examined 69 fully reprocessed endoscopes in 4 hospitals. Microbial cultures were positive for ≥50% of endoscopes. Researchers observed cloudy, shimmery fluid resembling simethicone inside channels and under a duodenoscope elevator mechanism. Crystallized white fragments were observed protruding from a gastroscope water jet outlet. Oily, sticky residue was found on endoscopes, and a 3-dimensional mass was found inside an endoscopic ultrasound endoscope. Hospital personnel reported the use of simethicone, cooking oil and silicone sprays, and tissue glue during endoscopy.

Discussion: The off-label use of defoaming agents, lubricants, and tissue glue is common and many endoscopists consider these products essential. Our findings suggest these substances are not removed during reprocessing and may impact reprocessing effectiveness.

Conclusions: Infection preventionists should determine whether these products are used in their institutions and evaluate methods for removing them. New policies may be needed to support procedural success and effective endoscope reprocessing.

1 Ofstead CL, et al. Widespread clinical use of simethicone, insoluble lubricants, and tissue glue during endoscopy: A call to action for infection preventionists. Am J Infect Control. 2019 Jun;47(6):666-670.

Simethicone Alternative

LIGHTBULB MOMENT?

Water Soluble Alternative

American Journal of Infection Control 51 (2023) 1192–1195

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Brief Report

A water-soluble alternative to simethicone for gastrointestinal endoscopy: Results of a clinical trial

Teri S. Mallard BSN, RN [a,*], Sandra S. Roswell MSN, BSN, RN [a], Evan P. Sylvester MPH, BS, CIC, MT (ASCP) [a], Cori L. Ofstead MSPH [b], James M. Scanlan PhD [c,d], John J. Brandabur MD [e], Amarnath V. Ramakrishnan MBBS, MD [a]

[a] Providence Swedish Medical Center, Endoscopy, Seattle, WA
[b] Ofstead & Associates, Inc., Bloomington, MN
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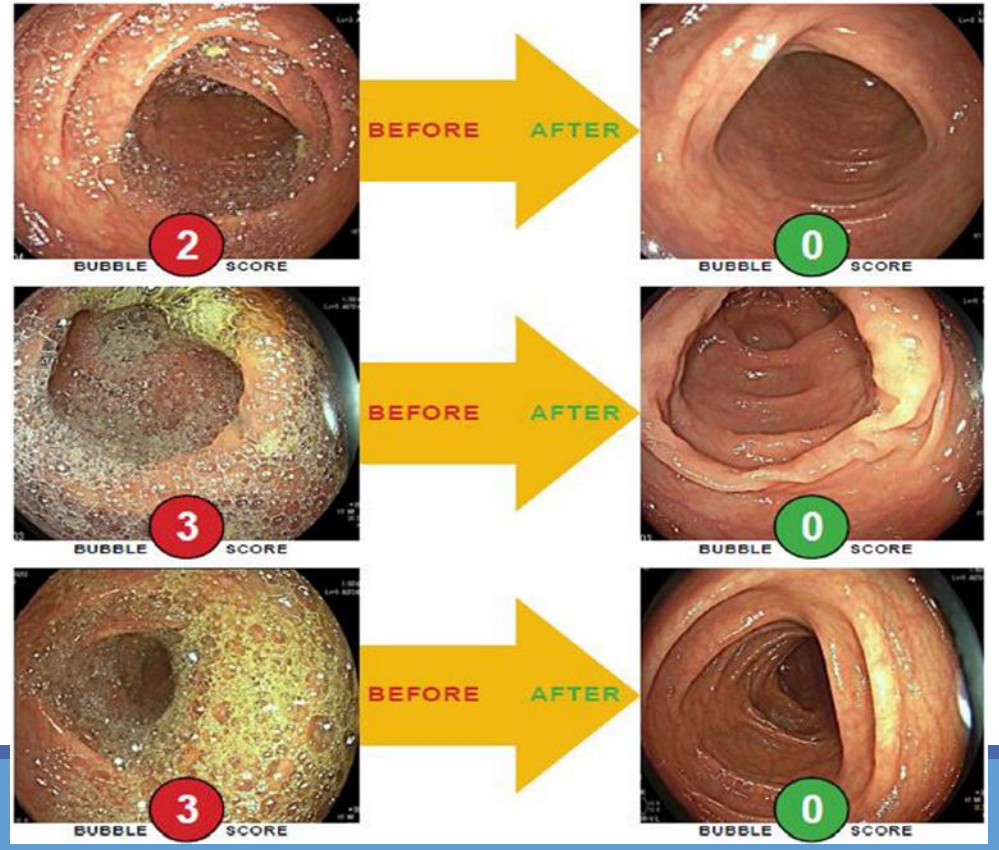
[d] Swedish Center for Research and Innovation, Swedish Medical Center Seattle, Seattle, Washington
[e] Providence Sacred Heart Medical Center, Spokane, WA

Key Words:
Colonoscope
Reprocessing effectiveness
Defoaming agent
Antibubble
Visualization
Biofilm
Colonoscopy

During endoscopy, simethicone defoaming agents are commonly used to improve visualization, but they leave residues and impact drying. This clinical trial involved patients undergoing colonoscopy procedures with substantial bubbles that impeded mucosal wall visibility. As an alternative to simethicone, investigators evaluated a water-soluble, ginger-based gastrointestinal supplement (GI-Ease) that did not contain sugars, thickeners, or binding agents. In 112/114 cases (98%), the bubbles were reduced sufficiently to allow visualization of the gastrointestinal tract, with no adverse events.



Independent research is being conducted to better understand the impact of this product on endoscope processing effectiveness.

What is this amazing alternative?

Google “simethicone alternative” and it is answer #4

Google “Simethicone Alternatives”

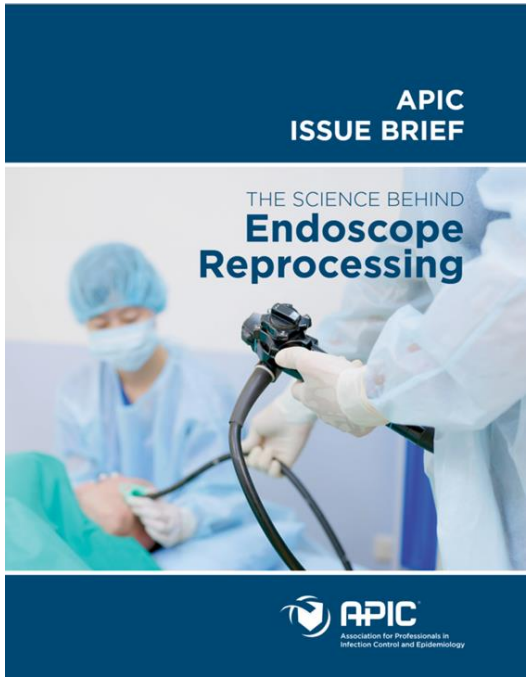
Additional Resources for Endo Processing

Healthmark Academy LMS

- https://academy.hmark.com/
- Monthly webinars
- 34 + CE approved programs
  - Many Endo programs

APIC Issue Brief: The Science Behind Endoscope Reprocessing

- https://apic.org/wp-content/uploads/2025/08/2025-APIC-Endoscope-Issue-Brief-02.pdf



CDC Essential Elements of Endoscope Processing

- https://www.cdc.gov/hicpac/media/pdfs/essential-elements-508.pdf

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Thank you!

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