Building Quality into Flexible Endoscope Reprocessing

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LIACS/MACSA

Disclosure

- I am an employee of **Healthmark Industries Fraser, Michigan USA**.
- I am involved with the manufacture and distribution of medical products to healthcare facilities and healthcare professionals.
- **No compensation** has been received for this presentation or for travel to and from the seminar.
- **All opinions are those of the presenter.**
- This presentation reflects the techniques, approaches and opinions of the individual presenter. This sponsored presentation is **not intended to be used as a training guide or promotion**. Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for the use of the device(s).

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Objectives

- Review best practices for manual cleaning of flexible endoscopes.
- Review rationale and current recommendations for cleaning verification.
- Identify the levels of inspection for flexible endoscopes and options to improve inspection through use of a borescope.

Importance of Cleaning

- The removal of all soil and organic material. Cleaning must precede disinfection/sterilization.

- Soil that remains on the endoscope may interfere with the ability of the disinfection/sterilization process to effectively destroy microorganisms and may contribute to biofilm formation.
  - Retained debris contributes to biofilm development (Fang et al., 2010) and interferes with the HLD capability to effectively kill and/or inactivate microorganisms (Roberts, 2013).

SGNA Reprocessing Steps

1. Precleaning
2. **Leak testing**
3. **Manual cleaning**
4. **Rinse after cleaning**
5. **Visual inspection (includes cleaning verification)**
6. High-level disinfection (manual or automated)
7. Rinse after high level disinfection
8. Drying (alcohol and forced air)
9. Storage

Remember you have 1 hour to Manual Cleaning!

- Enables processing personnel to ascertain how long the endoscope has been awaiting processing, to establish priority order, and to determine whether routine processing within the manufacturer's recommended time to cleaning is achievable, and if not, to implement the manufacturer's procedures for delayed processing.

- Note procedure end time/precleaning start time

- Method for conveying that time to reprocessing staff
  - AORN: IV.d.3. A procedure should be developed and implemented for recording the times that the procedure is completed and cleaning is initiated.

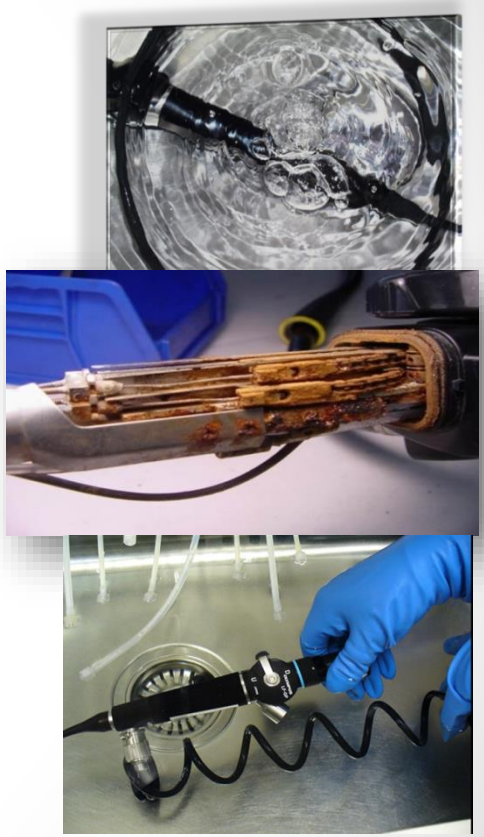
Delayed Reprocessing

- 1 hour hold time between precleaning & manual cleaning, and between manual cleaning & high-level disinfection

  - IFU: Soak for up to 1 hour surgical scopes & up to 10 hours for GI scopes
  - Olympus customer statement 2018: http://medical.olympusamerica.com/sites/default/files/pdf/delayedreprodifficultoclean.pdf
  - Reprocessing Manuals: Presoak for Excessive Bleeding and/or Delayed Reprocessing”

Best practices for Leak Testing

- Ensure fluid-resistant cap is on prior to submersion
- Use a basin of **water** large enough that the endoscope is not coiled too tightly to mask holes
- Allow for sufficient time to observe the endoscope for leaks, manipulate knobs and buttons, flex the scope
- Flush with syringe full of water to remove trapped air

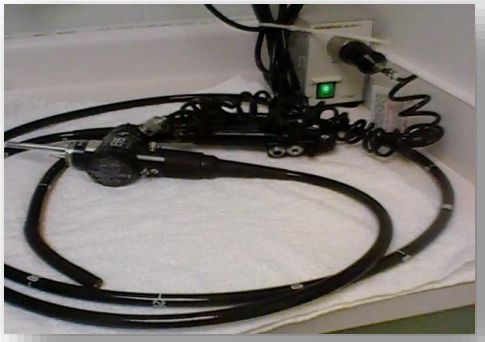


Common Leakage Testing Errors

- Not performed every cycle
- Moisture in connector or water-tight cap
- Soapy or reused water
- Too small sink (< minimum 16x16)
- Entire scope not immersed
- Not flushing with syringe of water
- Scope not pressurized before immersion
- Angulation controls and switches not manipulated
- Performed too quickly (30 seconds at least)
- Scope not properly depressurized
- Leaking scopes not properly HLD or ETO

Check your leak testers!

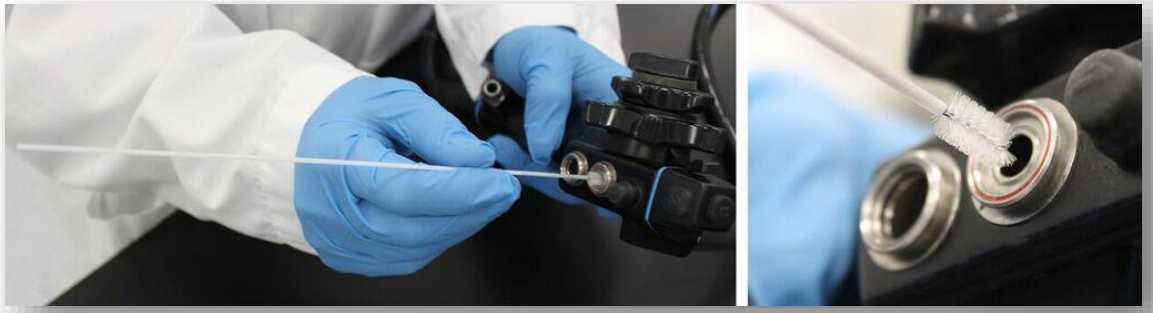
- Faulty leak tester are an Infection Control risk
- Incorrect pressure output is a common repair issue
- Push the button on the connector to hear hiss each time its used
- Check pressure on these
  - Pressure gauge or repair company
- Send for repair if not functioning properly



Best practices for manual cleaning

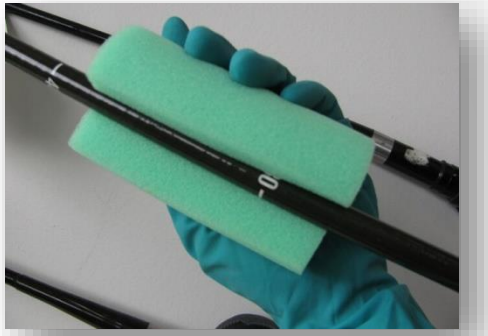
Cleaning steps:

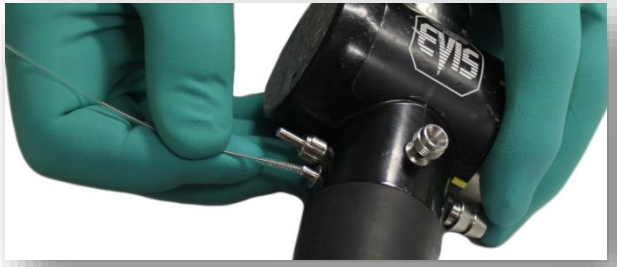
- Clean with a single-use lint-free cloth/sponge
- Submerge scope to prevent splashing contaminated fluids
- Use a cleaning brush with specifications per manufacturer's IFU
- Brush all channels, cylinders, openings and forceps elevators per IFU
- Suction???



Best practices for manual cleaning

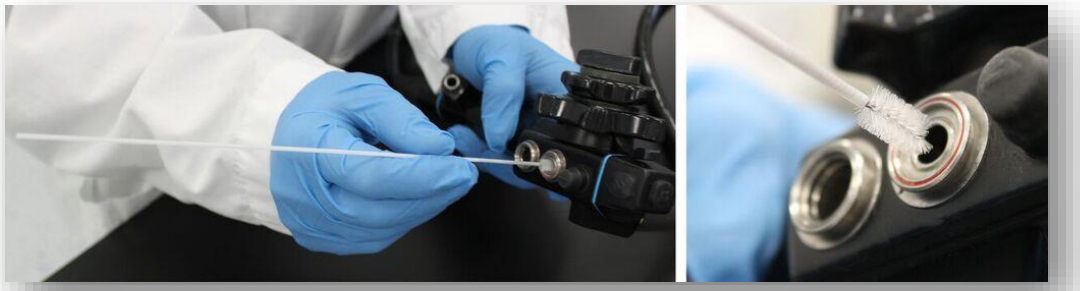
- Cleaning steps (continued):
  - Use recommended cleaning adapters
  - Flush all channels, rinse all channels, air purge all channels
  - Repeat until there is no visible debris
  - Soak, scrub, brush & rinse all reusable/removable parts
  - Automated flushing pumps may be used during manual cleaning





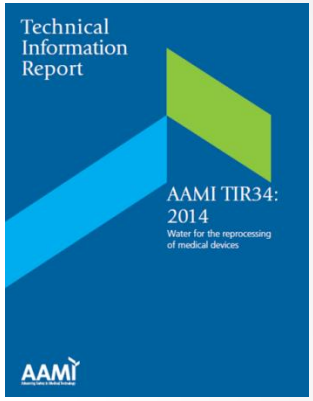
Brushes

- SGNA:
  - Have available appropriate size channel cleaning brushes
  - Use a brush size compatible with each channel
  - Endoscope cleaning brushes should be the appropriate size that assures contact with the surface (Peterson et al., 2011; Rutala et al., 2008)
- AORN:
  - All accessible channels and the distal end of the endoscope should be cleaned with a cleaning brush of the length, width, and material recommended by the endoscope manufacturer.



Rinsing after cleaning

- Thoroughly rinse with copious volumes of water (AAMI TIR34 – Utility water)
- Follow IFU of endoscope & cleaning solution to determine the amount of water needed for rinsing, psi/pressure, and number of rinses
- Use recommended cleaning adapters
- Rinse all external and internal surfaces
- Perform an air purge of all channels
- Dry exterior with a lint-free cloth/sponge
- Keep detachable valves together with the same endoscope as a unique set



Automated flushing systems

- If a flushing pump is used, follow manufacturer's written IFU
- Ensure compatibility of endoscopes with model of flushing system
- Use fresh solution with each endoscope
- Clean and disinfect tubing and equipment according to manufacturer's IFU
- Perform any other QA testing as recommended (e.g. daily volume verification)

Single-use vs Reusable Valves

- ST91, SGNA, AORN all recommend keeping reusable valves together with the scope through reprocessing – as a unique identifiable set
- Tracking IS difficult (not serialized, may have multiples)
- Consequences: many facilities moving to single-use valves

SGNA Reprocessing Steps

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Verification Tests

- Cleaning verification tests serve as a marker to show that the steps for reprocessing followed resulted in an adequately cleaned endoscope.

- Given the issues with endoscope reprocessing, cleaning verification tools have become critically important as a means to demonstrate that the cleaning process has achieved the goals of validated reprocessing instructions.

Best Practices for Endoscope Inspection and Cleaning Verification

- Inspection of endoscopes should include:
  - A visual inspection (ideally enhanced inspection); and
  - Cleaning verification processes.

- Cleaning verification is performed following cleaning to verify the effectiveness of a cleaning process **PRIOR TO DISINFECTION.**

- Use of methods to detect organic residue should be considered.

AAMI ST91 Cleaning Verification

- Cleaning verification is performed FOLLOWING CLEANING to verify the effectiveness of a cleaning process PRIOR TO DISINFECTION
- Residual organic soil and microbial contamination may be present on an accessible surface even though the device looks clean.
- The use of methods that are able to quantitatively or chemically detect organic residues that are not detectable using visual inspection should be considered and included in facility policies and procedures on device cleaning
- Lists commonly used cleaning verification products:
  - Protein, Carbohydrate, Hemoglobin, ATP

SGNA Cleaning Verification

- To confirm the adequacy of manual cleaning, a rapid cleaning monitor (or rapid audit tool) for residual organic soil can be used prior to high-level disinfection.
- If the tool results are positive, this allows for the re-cleaning of the endoscope prior to disinfection.
- Rapid cleaning monitors are available and can provide documentation on cleaning efficacy but do not reflect microbial activity.
- Real-time testing of endoscope lumens/elevator channel should be done immediately after manual cleaning so that any improperly cleaned devices are re-cleaned prior to HLD. Facilities should consider the use of monitors to verify ongoing cleaning adequacy.

AORN Cleaning Verification

- Manual cleaning of flexible endoscopes should be verified using cleaning verification tests when new endoscopes are purchased and at established intervals.
- Since manual cleaning is a learned skill subject to human error. Cleaning verification tests are used to **verify** the ability of the cleaning process to remove, or reduce to an acceptable level, the organic soil and microbial contamination that occurs during use of a reusable device.
- Periodic verification of cleaning effectiveness may help reduce errors in manual cleaning and improve effectiveness.
- There is a need for rapid testing methods to detect residual soil and verify the adequacy of manual cleaning.

Cleaning verification –

FREQUENCY recommendations

Current recommendations support testing of the manual cleaning process at pre-established regular intervals:

- AAMI ST91: Regular intervals, i.e. **Weekly or preferably daily**
- AORN: Regular intervals such as with **EACH reprocessing cycle** or daily
- SGNA: Confirm the adequacy of manual cleaning by using a rapid cleaning monitor. If the tool results are positive, this allows for the re-cleaning of the endoscope prior to disinfection. **Frequency determined by facility.**

Manual Cleaning Verification Monitors

Channel Sample

Flush methods

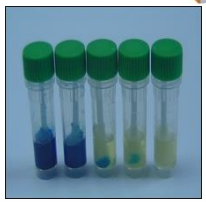
Combination test strips

Carbohydrate, protein & hemoglobin

Swab methods

Protein swabs

Hemoglobin swabs



ATP Systems

Detects ATP

Flush and swab methods

Many systems available

EndoChecks

EndoCheck Hemoglobin (EDH)

- Blood detection as low as 0.1 µg
- Distinct pass/fail colors
- 30 seconds read time
- Positive result (blue-green)

EndoCheck Protein (EDP)

- Protein detection as low as 1 µg
- Distinct pass/fail colors
- 5 minute read time
- Positive result (blue-green)

ChannelCheck Specifics

SCIENCE & METHOD were developed by a microbiologist – Dr. Michele Alfa, U of Manitoba, Canada

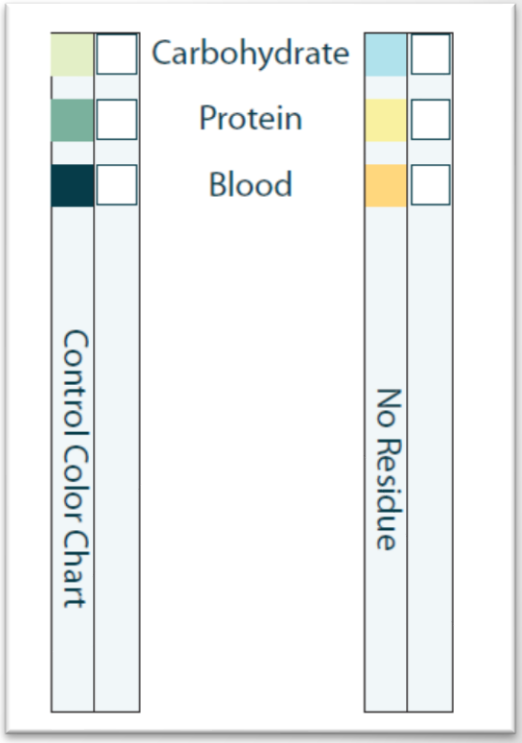
- Conducted an extensive study
- 25 sites - 1100 plus tests.
- Demonstrated that 17% of scopes are still dirty after initial cleaning.

ChannelCheck Info

- Tests 3 soils at once: blood, protein and carbohydrates
- Can test virtually any instrument – lumened or not – rigid or flexible no matter the diameter
- Can be used on every scope, every channel
- Minimum recommendation is daily.
- Instructions available for flushing each channel/port/forceps elevator, valves, adapters

ChannelCheck Procedure

1. Flush an individual channel with 10ml sterile-DI water
2. Capture the water in a clean (preferably sterile) container.
3. Dip and swish the test strip in the recovered water for 10 seconds.
4. Remove the strip, wait **90 seconds** and then compare the color of the pads to the results chart.
5. Any positive reaction = RECLEAN and retest



Inspection of Flexible Endoscopes

- AAMI - ST 79 and ST 91
- AORN
- SGNA

All support the practice of using some type of basic visual inspection with the unaided eye

Overview - LEVELS of Inspection

- All scopes must be visually inspected after manual cleaning: Look for debris and damage
- Standards and professional guidelines also call for lighted magnification to be used for this step
- Cleaning verification tests are used to check for internal retained patient debris
- AAMI and AORN recommend use of a borescope for internal inspection

BASIC visual inspection - the UNAIDED eye

- The most basic verification of the performance of a cleaning process is by carefully inspecting the cleanliness of instruments and materials with your eyes.
- All objects should be free of any remaining soils, deposits, pitting etc.
- **Olympus 180 duodenoscope IFU**:
  - "Inspect whether there is debris on the forceps elevator and in the forceps elevator recess while raising and lowering the forceps elevator, and repeat brushing and/or flushing the forceps elevator and the forceps elevator recess until no debris is observed upon the inspection."
  - Inspect all items for residual debris. Should any debris remain, repeat the entire cleaning procedure until all debris is removed.

Example IFUs – Olympus CYF-5 & 5A

3.2 Preparation and inspection of the endoscope

Clean and disinfect or sterilize the endoscope as described in Chapter 5, "Reprocessing: General Policy" through Chapter 7, "Cleaning, Disinfection and Sterilization Procedures".

Inspection of the Endoscope

1. Visually inspect the control section and the light guide connector for excessive scratching.
2. Visually inspect the boot and the insertion tube near the boot for bends, twists or other irregularities.
3. Visually inspect the external surface of the entire insertion tube for dents, bulges, swelling, peeling or other irregularities.
4. Holding the insertion tube gently with a hand carefully run your fingertips over the entire length of the insertion tube in both directions (see Figure 3.2).
   Confirm that there is no object stopping the hand or protruding objects or other irregularities.

SGNA – endoscope inspection

- Treat as a safety stop or “time out” to ensure the endoscope is visually clean before proceeding to the next step of HLD.
- Visually inspect for conditions that could affect the disinfection process (e.g., cracks, corrosion, discoloration, retained debris).
- Repeat manual cleaning step(s) if not clean.
- Minimum standard for cleaning assessment of scopes.
- Need adequate lighting

AORN - visual inspection

- Visually inspect with lighted magnification for cleanliness, integrity, and function before use, during the procedure, after the procedure, after cleaning, and before disinfection or sterilization.

- Inspection helps to identify residual organic material and defective items and remove from service soiled / defective items that might put patients at risk for infection or injury.

AAMI ST91 - visual inspection

- Careful visual inspection should be conducted to detect the presence of any residual soil.
- Users should inspect every device for visible organic soil and contamination in a simple functionality test.
- Direct visual inspection is not always possible for the inner components of medical devices that have lumens.
- Use lighted magnification and inspect throughout process

APIC - Duodenoscope Inspection

- Because duodenoscopes are more complex than other endoscope instruments, it requires meticulous attention to detail and step-by-step precision to render them safe for re-use.

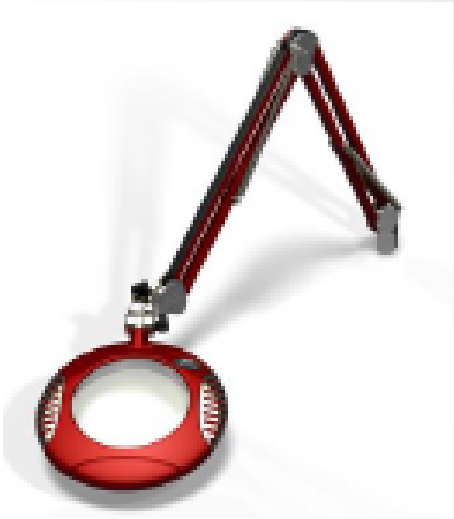
- After observing the cleaning and disinfecting processes and asking questions so that each step of the process is understood, the IP or HE may visit the department regularly to observe scope cleaning practices and reinforce the importance of the work being done.

- The IP or HE will evaluate human factors, including ensuring that the cleaning area is set up with a bright light and magnification so all sections of the scope being cleaned can be well visualized.

http://www.apic.org/Resource_/TinyMceFileManager/mediaImages/ERCP_Press_Release_APIC_SHEA_02242015.pdf

CDC - visual inspection

- Ensure that the elevator mechanism is thoroughly cleaned and free of all visible debris.
  - Visual inspection is to be done with the elevator in the “open/raised” position and “closed/lowered” position to ensure there is no visible debris above or below the elevator mechanism.



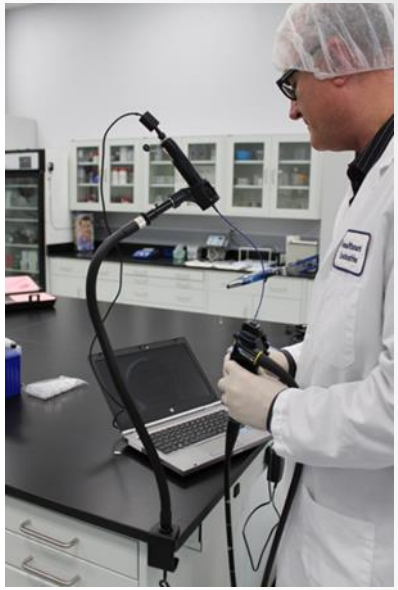
- Consideration should be given to use of a magnifying glass (e.g., 10x) to improve detection of residual debris around the elevator mechanism

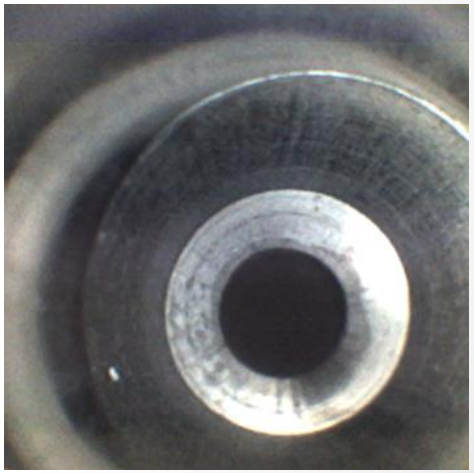
FDA - visual inspection

- All routine cleaning instructions should include instructions for visual inspection, which may include use of magnification and adequate lighting. The instructions should advise the user that if the device is determined not to be visually clean at the end of the cleaning step, the user should either repeat the relevant previous cleaning steps or safely dispose of the device.
- Additionally, the visual inspection instructions should identify acceptance or failure criteria related to device performance (e.g., unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals), as well as instructions to properly dispose of devices that fail.

Endoscope borescopic inspection

- Used in major research papers.
- Not **required** in any endoscope IFUs at this time – "may be used" (AAMI & AORN).
- **Tougher wording in draft AAMI ST91.**

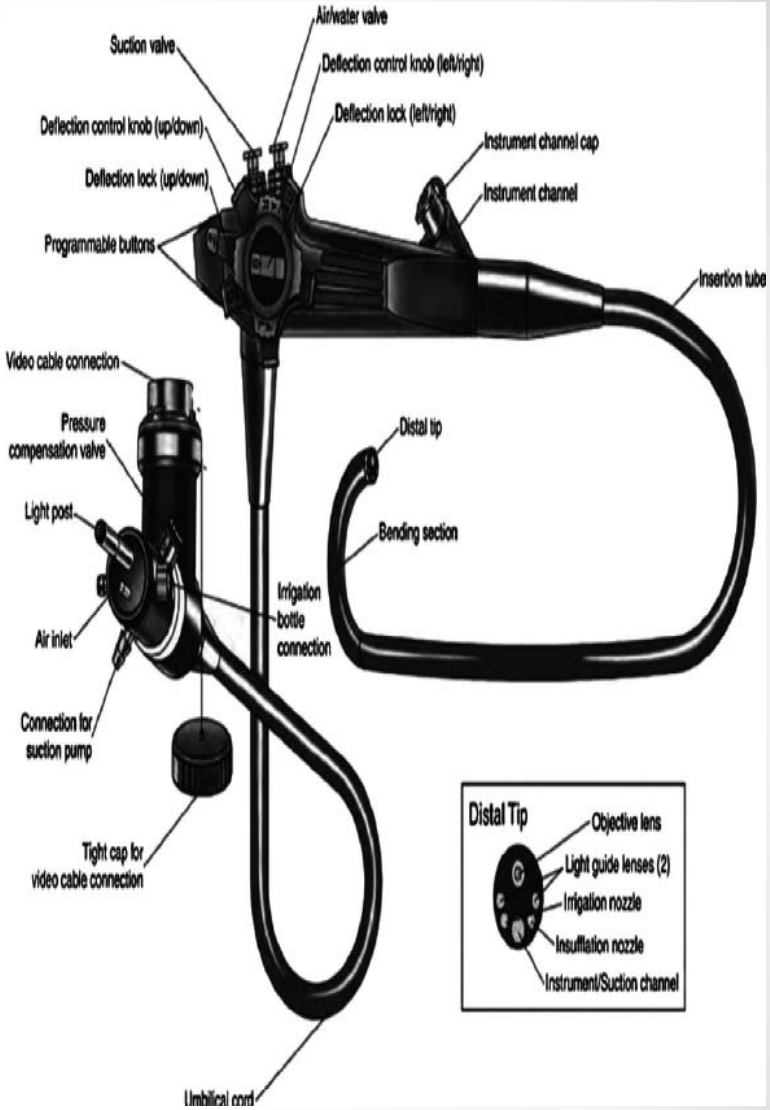




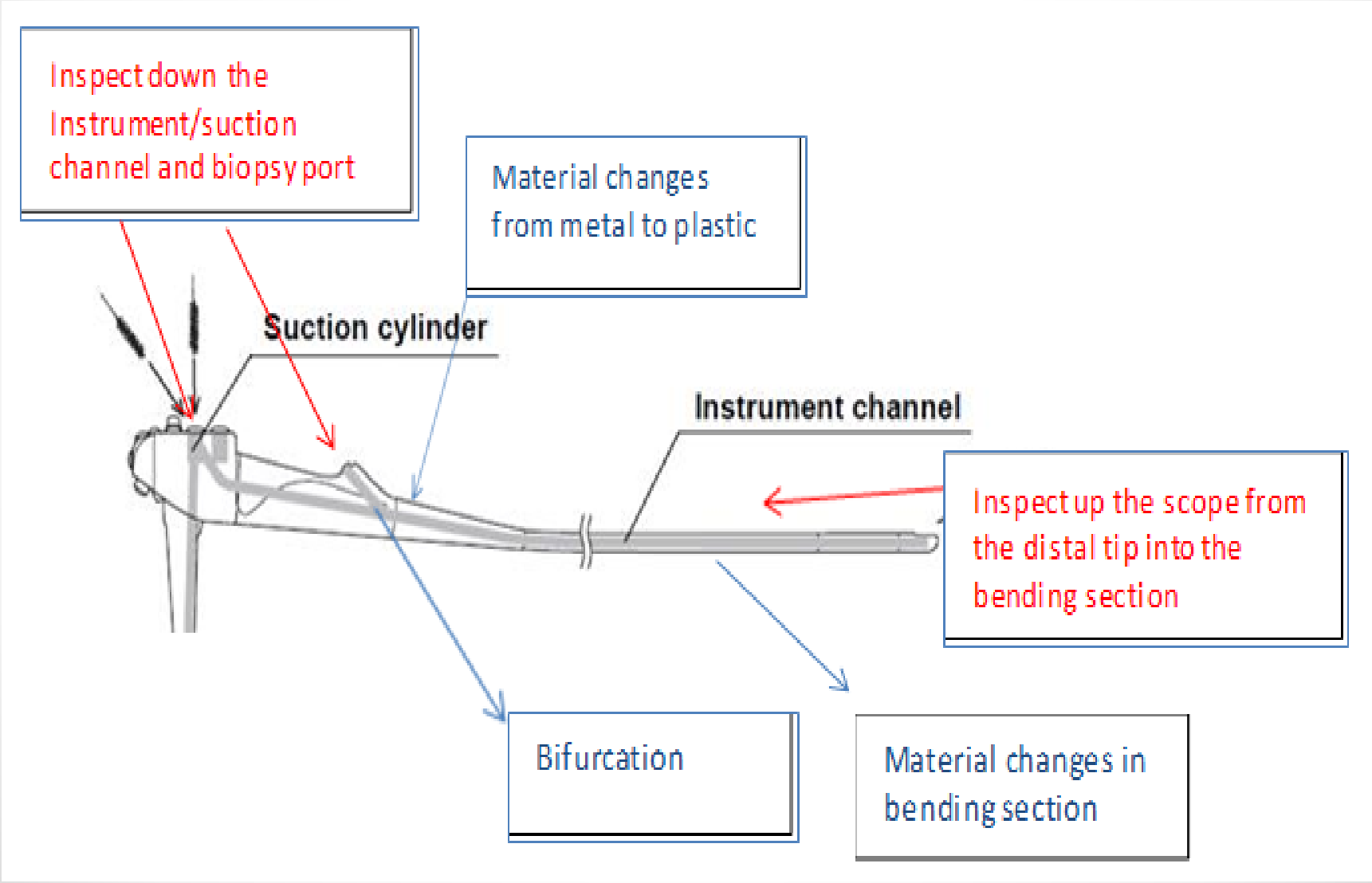
New biopsy area

WHERE to inspect in a scope

- Instrument/suction channel
- Valve openings
- Distal tip
- Around control knobs
- Forceps elevator (if present)
- Accessories

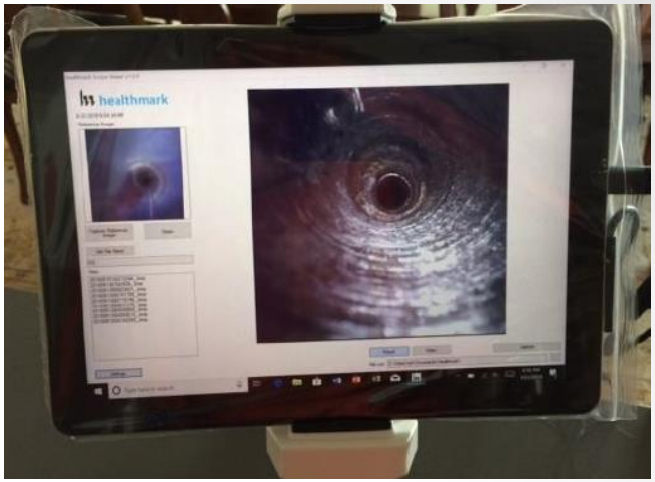


Where to inspect in a scope



Inspection entails ALL parts of the scope

WHEN to inspect with a borescope?



- Two options that facilities are currently employing based on their logistics and workflow:
  - After manual cleaning prior to disinfection
  - After reprocessing is complete and the scope is in storage

Borescope AFTER MANUAL CLEANING and prior to disinfection

- Dirty procedure

- Borescope must be processed between uses in accordance with the IFU
  - Wipe with surface disinfectant wipes
  - Can disinfect or sterilize dependent on model.

Borescope AFTER DISINFECTION and/or endoscope is in storage

- Clean procedure
- Borescope must be reprocessed after use
- Endoscopes must be completely reprocessed after inspection (rerun through cleaning and disinfection)
- Used as a quality tool to inspect endoscopes on a periodic interval established by the facility
- Looking for retained debris, damage and moisture
  - Endoscopes should be dry at this point since they are in storage!

Borescopes – options

- Many different types of borescopes are available
- Various sizes
- Make sure to know endoscope inventory - to pick the correct size borescope
- Video and fiber scopes available
- Different manufacturers
- Different chemical compatibilities
  - Disinfection
  - Sterilization

What are we actually looking at?

- GET A BASELINE - take photos or videos of new scopes to compare to later
- Remember - people become used to what they see over time
- Review latest research findings to help in decisions of what's critical and what's non-critical for inspection
- More info to come (ST91)

OLYMPUS

December 8, 2017

Re: Use of borescopes for cleaning verification of Olympus flexible endoscopes

Dear Health Care Professional,

This letter is in response to your recent inquiry on the use of borescopes for cleaning verification of Olympus flexible endoscopes.

Olympus does not currently have an official stance on the use of borescopes as a tool for visualization of flexible endoscope channels after manual cleaning. We are aware that several industry guidelines have a recommendation regarding the use of borescopes. However, as the endoscope manufacturer, Olympus neither requires nor prohibits the use of borescopes. Please refer to the Instructions for Use of the specific endoscope model for validated reprocessing instructions.

WARRANTY
Nothing contained in this letter alters, extends, or modifies in any way the authorized Olympus warranty applicable to each device or instrument.

If you have any additional questions, please contact your local Olympus sales representative or the Olympus Technical Assistance Center at 1-800-848-9024 (United States) or 1-800-387-0437 (Canada).

Sincerely,

Olympus

Articles & research continue to reinforce significance of borescope inspections

Original Articles

Clinical Endoscopy

Scoping the scope: endoscopic evaluation of endoscope working channels with a new high-resolution inspection endoscope (with video)

Monique T. Barakat, Mohit Girotra, Robert J. Huang, Subhas Banerjee
p601–611.e1
Published online: February 6, 2018

Full-Text HTML | PDF | Supplemental Materials

Inspection of endoscope instrument channels after reprocessing using a prototype borescope

Adarsh M. Thaker, Stephen Kim, Alireza Sedarat, Rabindra R. Watson, V. Raman Muthusamy
p612–619
Published online: May 9, 2018

Full-Text HTML | PDF

Borescope examination: Is there value in visual assessment of endoscope channels?

Kavel Visrodia, Bret T. Petersen
p620–623
Published in issue: October 2018

Full-Text HTML | PDF

Support for using enhanced visual inspection – Poster at AORN 2017

Multisite study on ureteroscope reprocessing effectiveness

Cori L. Ofstead, MSPH[1]; John E. Eiland, RN, MS[1]; Otis L. Heymann, BA[1]; Mariah R. Quick, MPH[1]; Harry P. Wetzler, MD, MSPH[1]
[1]Ofstead & Associates, Inc., Saint Paul, MN, USA

Introduction and purpose

- Contaminated duodenoscopes, gastroscopes, bronchoscopes, and cystoscopes have been linked to outbreaks[1,2]
- Damaged or contaminated ureteroscopes have also caused injuries and infections[3-5]
- Functional failures discovered during procedures or reprocessing lead to frequent repairs[6,7]
- Current guidelines recommend careful visual inspection during reprocessing[1,2]
- This study sought to answer the following research questions:
  - How much contamination can be detected in sterilized flexible ureteroscopes?
  - How much damage or debris is visible when using lighted magnification?

Methods

- Prospective study conducted in two large institutions
- The research team:
  - Audited reprocessing practices
  - Obtained samples using surface swabs and a flush-brush-flush technique
  - Performed tests for residual contamination:
    - Protein, hemoglobin, and adenosine triphosphate (ATP)*
    - Microbial cultures
  - Conducted visual inspections of:
    - External surfaces using lighted magnification and a digital camera
    - Channels and ports using a 0.8 mm fiber optic borescope

*Published benchmarks for manually-cleaned gastrointestinal (GI) endoscopes were used since there are no benchmarks for permissible contamination levels on sterilized ureteroscopes

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Results

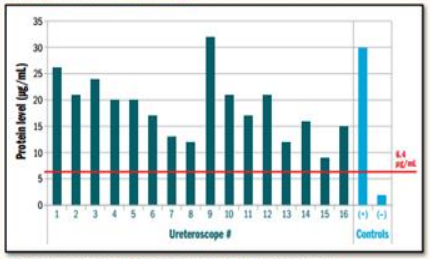
- Flexible ureteroscope characteristics (N=17):
  - Average age 2.1 years
  - Repairs required after an average of 19 uses due to:
    - Failed leak tests
    - Inadequate image quality
    - Broken fibers
    - Pinched insertion tubes
- Reprocessing involved:
  - Manual cleaning by reprocessing technicians
  - Sterilization with hydrogen peroxide gas
- Audits found both sites had inadequate processes for:
  - Bedside pre-cleaning by OR staff
  - Visual inspection by OR and reprocessing staff
  - Drying prior to sterilization
- Examinations found visible irregularities (Photos 1-3) and contamination on 100% of ureteroscopes (Table 1, Figure 1)

Table 1. Results of visual inspections, biochemical tests, and microbial cultures (N=16*)

Test	Benchmark	Number (%) above benchmark
Visual inspection	No damage or debris	16 (100%)
Protein	6.4 µg/mL	16 (100%)
Hemoglobin	2.2 µg/mL	1 (6%)
ATP	200 RLU†	1 (6%)
Microbial cultures	No growth	2 (13%) *Micrococcus luteus* *Corynebacterium glaucum*

*One ureteroscope was out for repair during the site visit †RLU: relative light units

Figure 1. Protein levels on sterilized ureteroscopes



Red line = "clean" benchmark; Controls: dirty ureteroscope (+); brand new ureteroscope (-)

Photo 1. Channel port with rusty discoloration; oily deposits and white, foamy residue near port

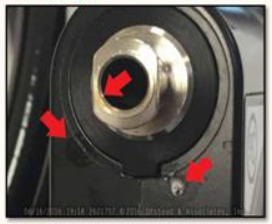
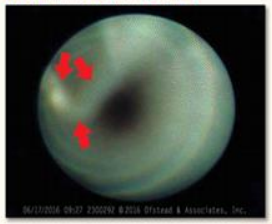


Photo 2. Scratches and gouges surrounding channel port

Photo 3. Filamentous debris protruding into channel



Summary and next steps

Sterilized ureteroscopes had high contamination levels, visible damage, and debris

- Tests conducted on sterilized flexible ureteroscopes found:
  - All had visible irregularities
  - All had contamination above benchmarks for clean GI endoscopes
  - Two (13%) had positive microbial cultures
- Results highlight the need for:
  - Improvement in adherence to guidelines, including:
    - Bedside pre-cleaning by OR staff to prevent buildup of residue
    - Biochemical tests that verify cleaning effectiveness
    - Visual inspections with lighted magnification to identify irregularities
  - More frequent preventive maintenance
  - Reprocessing methods that are proven effective to ensure patient safety

Disclosures and acknowledgements

The study was conducted independently by researchers from Ofstead & Associates, Inc. and personnel from two study sites. Boston Scientific Corporation provided a research grant, and Healthmark Industries and 3M Company provided study materials. The study sponsors did not have access to the data nor participate in developing the content of this poster.

References

1. AORN Guideline for processing flexible endoscopes; 2016.
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3. Chang CL, et al. *J Hosp Infect*; 2013.
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Support for using enhanced visual inspection – Poster at AORN 2016

Residual contamination found on endoscopes in an ambulatory surgery center

Cori L. Ofstead, MSPH[1], John E. Eiland, RN, MS[1], Miriam R. Amelang, BA[1], Otis L. Heymann, BA[1], Sarah B. Held, RN, MBA[2], Michael J. Shaw, MD[3]

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Introduction

- Contaminated endoscopes have caused outbreaks of multidrug-resistant organisms[1-5]
- During one outbreak investigation, investigators dismantled an endoscope and identified:[5]
  - Brown staining, scale, and a small crack in the distal tip
  - *Pseudomonas aeruginosa* identical to outbreak strain
- In another outbreak investigation:[2]
  - Infections were tied to contaminated endoscopes
  - The manufacturer found critical defects in every duodenoscope
- This study was designed to answer two questions:
  - How much do damage and debris accumulate in endoscopes over time?
  - Is it possible to get old endoscopes clean?

Methods

- Longitudinal study in an ambulatory surgery center
- Three assessments conducted over a 7-month period
- Baseline data collection in April 2015:
  - Auditing reprocessing practices
  - Compiling data on endoscope age, usage, and repair history
  - Evaluating 17 clinically-used endoscopes:
    - Rapid indicator tests for ATP and protein
    - Microbial cultures
    - Borescope examinations of interior components
- Implementation of more rigorous reprocessing methods (beginning in May 2015)*

*Results of routine monitoring and follow-up assessments pending

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Results

At the baseline assessment:

- All endoscopes were < 2.5 years old
- Endoscopes had been used 36-541 times
- Nine endoscopes had been repaired
- There was good adherence to reprocessing policies
- 16 of 17 endoscopes were still contaminated after manual cleaning
- Contamination levels were higher for gastroscopes than colonoscopes (Figures 1 and 2)
- Borescope examinations of patient-ready endoscope channels identified:
  - Residual fluid (Photos 1 and 2)
  - Irregular surfaces and brown staining (Photo 3)
  - Scratches, non-intact lining, and brown staining (Photo 4)
- Among endoscopes tested after high-level disinfection:
  - 71% failed to meet criteria for patient-ready endoscopes**
  - 29% harbored viable bacteria

**Criteria: No viable microbes and ATP and protein levels below "clean" benchmarks

Photo 1. Fluid inside the biopsy port of a gastroscope

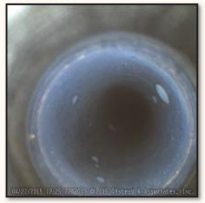


Photo 2. Fluid inside the suction/biopsy channel of a colonoscope

Photo 3. Irregular surfaces and brown staining inside the distal end of a colonoscope

Photo 4. Scratches, non-intact lining, and brown staining in the bending section of a colonoscope

Figure 1. ATP test results after manual cleaning

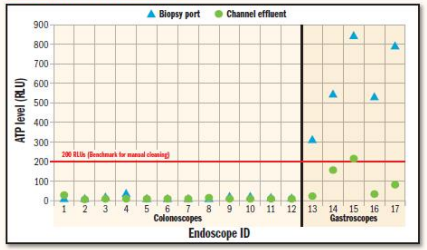
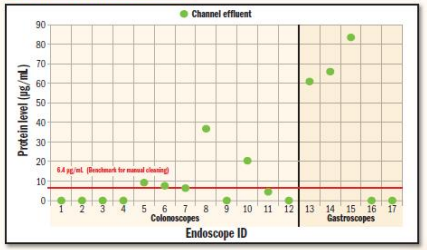


Figure 2. Protein test results after manual cleaning



Summary and next steps

Looking inside reprocessed endoscopes revealed damage and debris

- During the baseline assessment, researchers found:
  - Damage and debris inside channels
  - Contamination levels exceeding benchmarks
  - Residual fluid in channels and ports
- Findings indicated that current reprocessing methods were not sufficient
- Interventions included:
  - Sending endoscopes out for repair
  - Adopting more rigorous reprocessing practices
  - Implementing routine ATP monitoring of cleaning effectiveness
  - Increasing forced air drying times
- Results from the interim and final assessments are forthcoming
  - Observations from unannounced audits of reprocessing practices
  - Impact of interventions designed to improve reprocessing
  - Changes in contamination levels and visual appearance over a 7-month period

Disclosures and acknowledgements

The study was conducted independently by researchers from Ofstead & Associates, Inc., the University of Minnesota, and Fairview Maple Grove Medical Center. The study was supported in part by research grants from 3M Company, Medivators, Inc., and HealthMark Industries. Study sponsors did not have access to the data nor participate in developing the content of this poster.

References

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3. Marsh JW, et al. *PLoS One*. 2015;10(12):1-18.
4. Kovaleva J, et al. *Clin Microbiol Rev*. 2013;26(2):231-254.
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Poster at SGNA 2016

Reprocessing effectiveness for gastroscopes and colonoscopes: Longitudinal comparison of two methods

Cori L. Ofstead, MSPH[1], Harry P. Wetzler, MD, MSPH[1], Miriam R. Amelang, BA[1], Otis L. Heymann, BA[1], John E. Eiland, RN, MS[1], Sarah B. Held, RN, MBA[2], Michael J. Shaw, MD[3]

[1]Ofstead & Associates, Inc., Saint Paul, MN, USA; [2]Fairview Maple Grove Medical Center, Maple Grove, MN, USA; [3]Division of Gastroenterology, Department of Medicine, University of Minnesota Medical School, Minneapolis, MN, USA

1. Introduction

- Outbreaks have been linked to contaminated gastroscopes and colonoscopes[1-3]
- Investigators have identified endoscope defects during outbreaks[4,5]
- Study conducted to determine:
  - How much damage and debris accumulate over time?
  - Is it possible to get old endoscopes clean?
  - What is the effect of more rigorous reprocessing methods?

2. Methods

- Longitudinal study conducted over 7 months
- Standard reprocessing (control) compared with more rigorous methods (intervention) (Table 1)
- Baseline and interim data collection included:
  - Observation of reprocessing
  - ATP tests and cultures after cleaning and after HLD
  - Borescope examinations of channels

Table 1. Endoscope study groups

Reprocessing methods	Control	Intervention
Bedside pre-cleaning	✖	✖
Manual cleaning	✖	✖
Verification of cleaning effectiveness using ATP		✖
Repeat cleaning and HLD when ATP ≥200 RLU		✖
Automated cleaning in AER		✖
HLD with glutaraldehyde in AER	✖	
HLD with peracetic acid in AER		✖
Alcohol flush and forced air purge in AER	✖	✖
Vertical storage in ventilated cabinets	✖	✖

3. Results

- Baseline:
  - Manual cleaning and HLD commonly ineffective (Table 2)
  - Gastroscopes more contaminated than colonoscopes
  - Visible irregularities and residual fluid identified (Figures 1, 2)
- Interim:
  - Contamination and defects worsened over time
  - Discoloration reduced in intervention group (Figures 3, 4)
- Cleaning verification tests exceeded benchmarks:
  - 1% of colonoscope encounters (n=304)
  - 52% of gastroscope encounters (n=143) (Figure 5)

Table 2. Results for baseline and interim assessments

	Baseline (N=17)	Interim (N=19)	Interim results by group: Control (N=10)	Interim results by group: Intervention (N=9)
Post-cleaning ATP ≥200 RLU	29%	37%	30%	44%
Highest post-cleaning ATP (RLU)	841	2910	2910	1600
Positive cultures post-HLD	47%	58%	67%	50%
Number sent for repair*	2	4	2	2

*Due to study findings

Figure 1. Discoloration and scratches in a channel

Figure 3. Control: Persistent discoloration and debris in a distal end

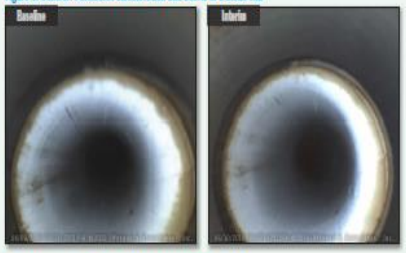


Figure 2. Residual fluid in a channel

Figure 4. Intervention: Reduction of discoloration in a distal end

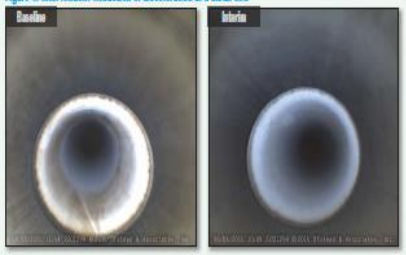
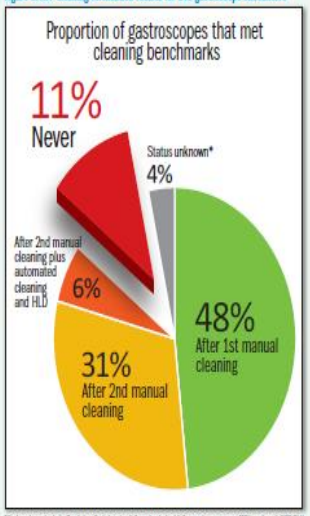


Figure 5. ATP cleaning verification results for 143 gastroscope encounters



*Tests not conducted after 1st or 2nd cleaning failure due to test failure or human error; ATP benchmark 200 RLU

4. Summary

Endoscope contamination accumulated over time

- Borescope examinations identified six endoscopes requiring repair
- Routine ATP tests detected endoscopes needing re-cleaning before HLD
- More rigorous reprocessing methods reduced discoloration

References

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3. England D. ICHE. 2016:1-2.
4. Wendorf KA. ICHE. 2015;36(6):634-642.
5. Verfaillie CJ. Endoscopy. 2015;47(6):493-502.

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Support for using enhanced visual inspection

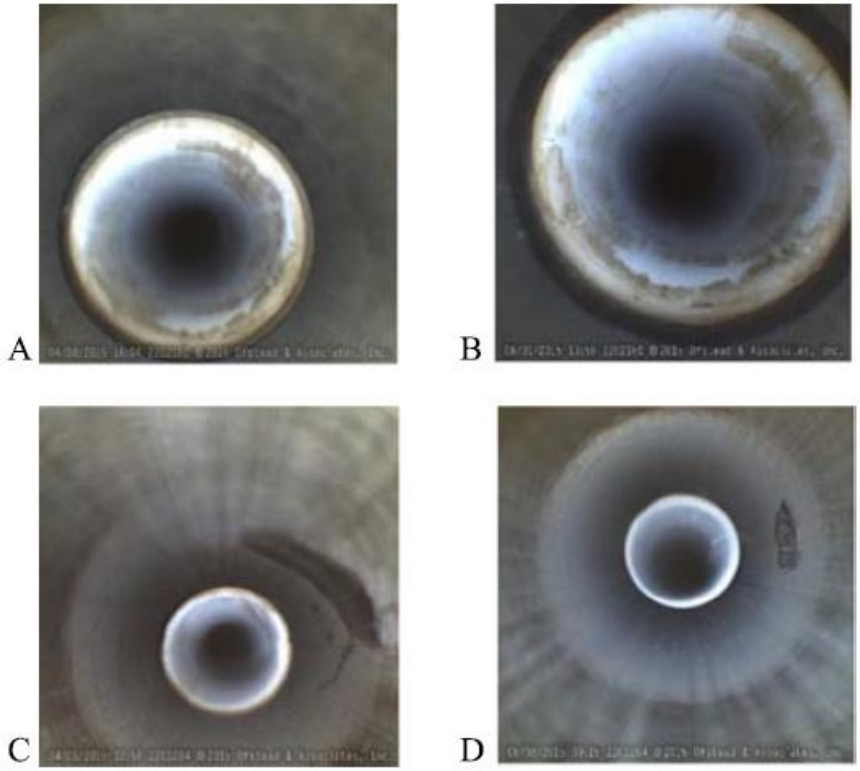
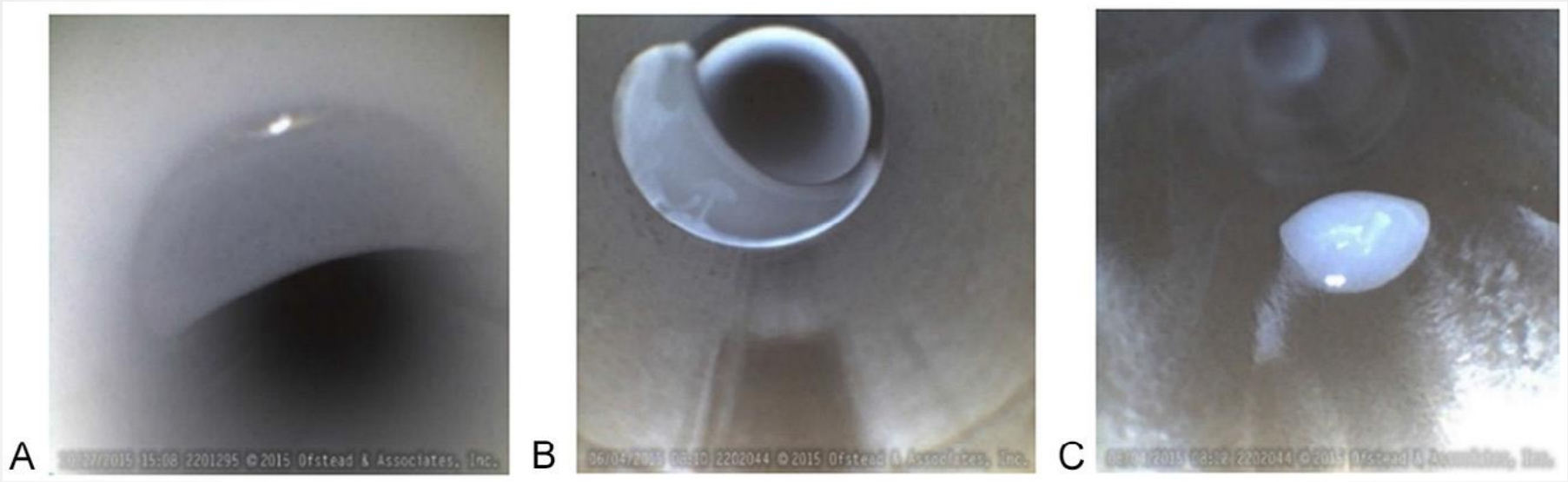


Fig 2. Discoloration and scratches observed. (A) In a control group colonoscope at baseline. (B) In the same control group colonoscope at 2-month assessment. (C) In an intervention colonoscope at baseline. (D) In the same intervention colonoscope at 2-month assessment.

- Borescope inspection identified scratches, discoloration, debris, & fluid
- Allowed damaged and contaminated scopes to be identified and reprocessed and sent for repair
- With repair, manufacturer determined there were critical defects

Reference; Ofstead and associates, AJIC 2016. Article in press.

Support for using enhanced visual inspection



Fluid and Simethicone residual identified in a scope after processing - in 19 of 20 scopes inspected

Reference: Ofstead and associates, AJIC 2016, article in press

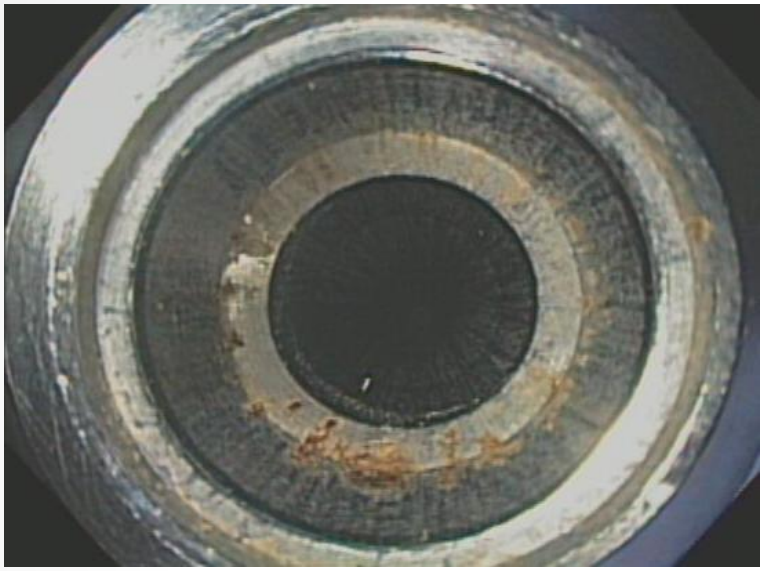
AAMI ST91

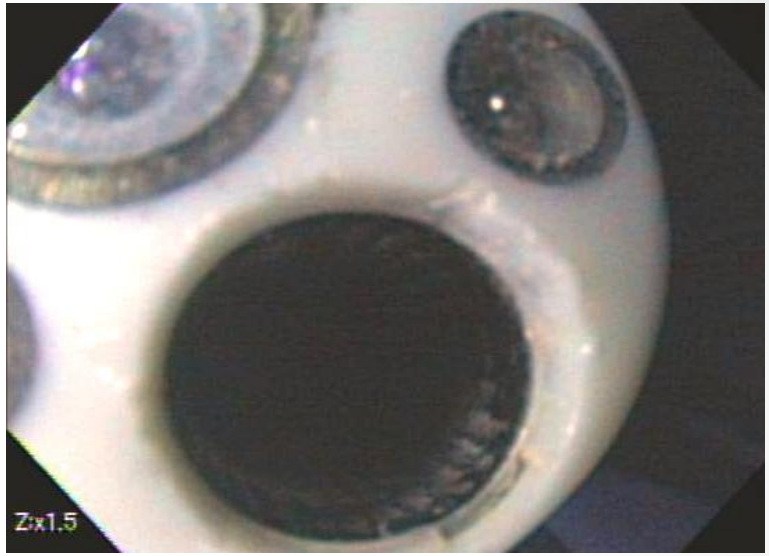
- Informative Annex Being Developed to help with interpretation of results.

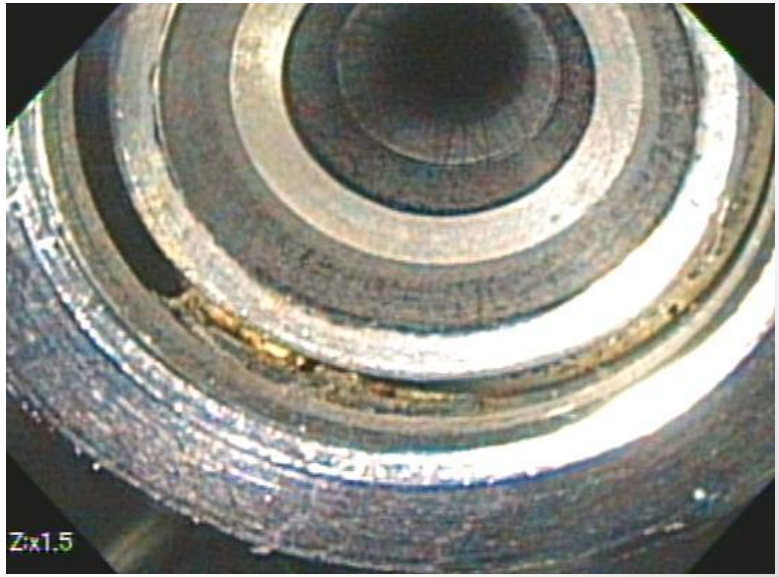
- Will include:
  - Photos
  - Where to inspect

Interpretation: Photos taken with a borescope

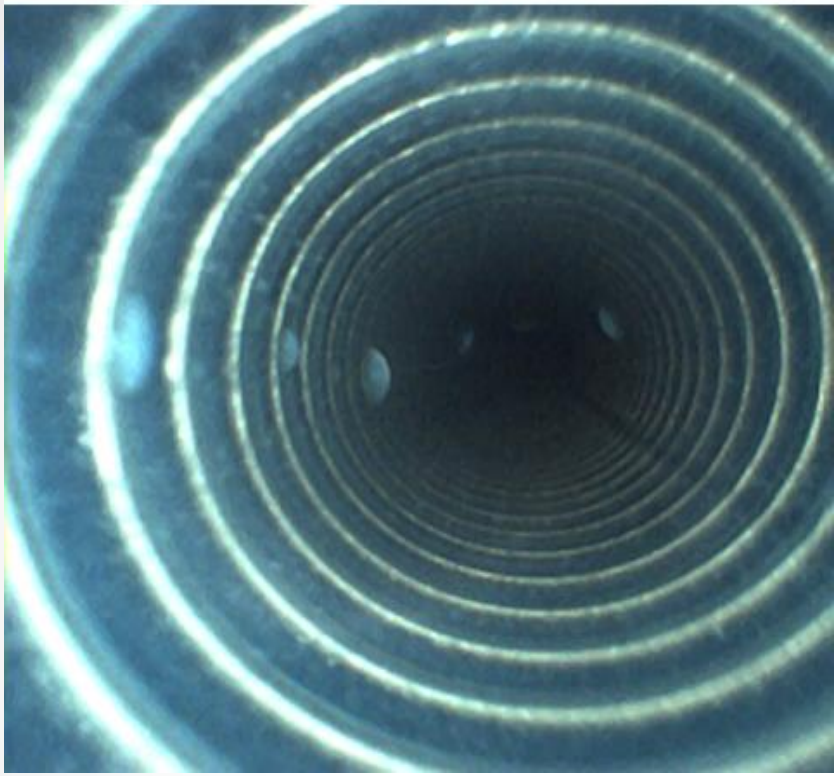
Examples of Debris and Damage Found in Endoscopes.



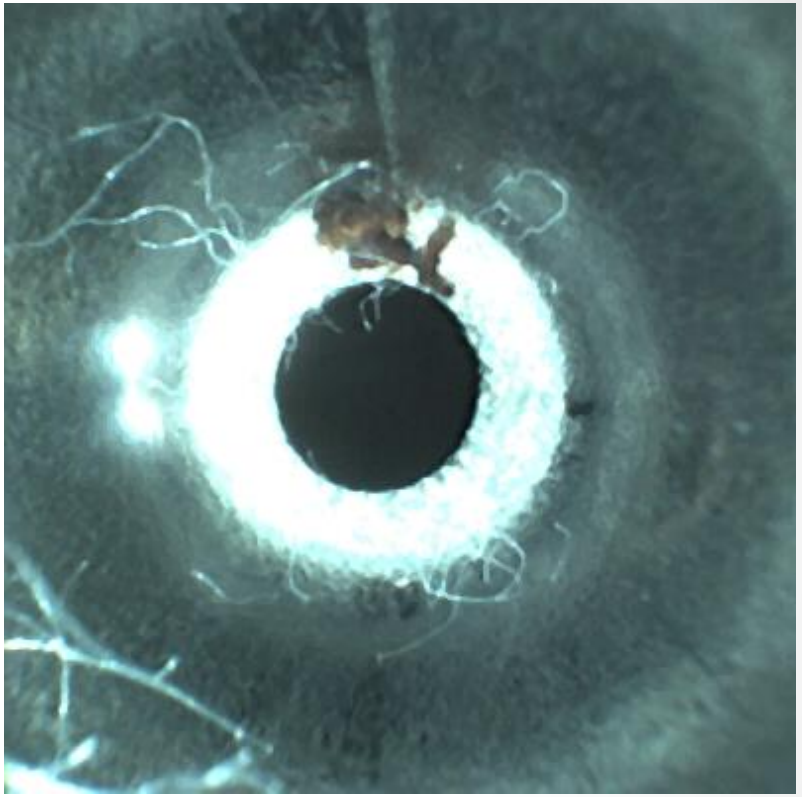




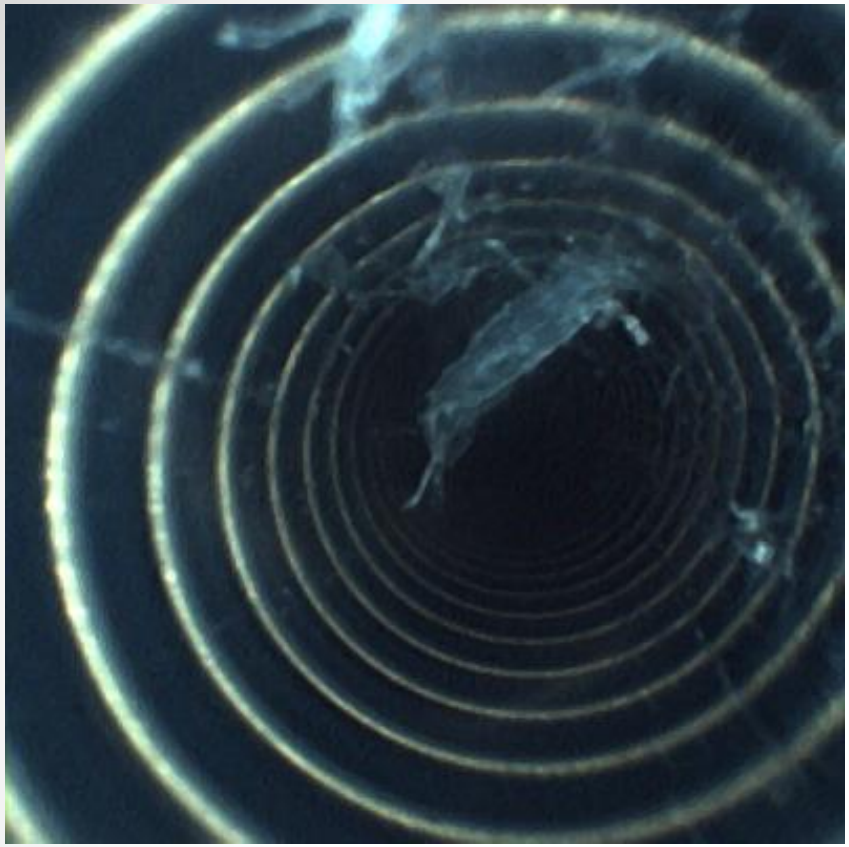
Borescope Examination Photos using the FIS

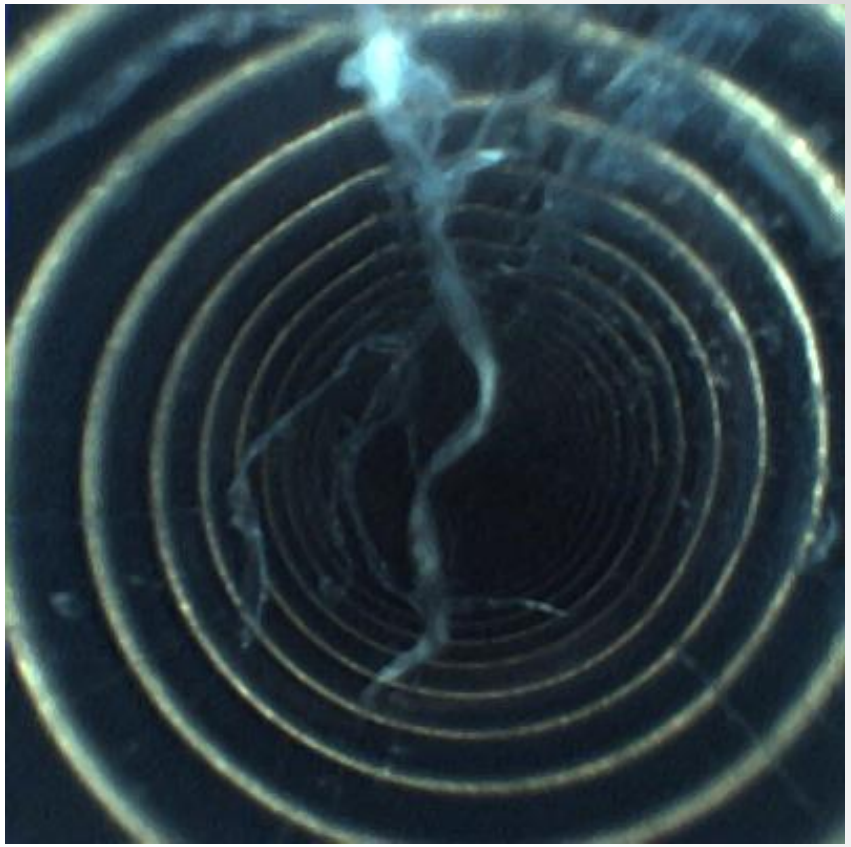


Fluid in Channel of “DRY” scope



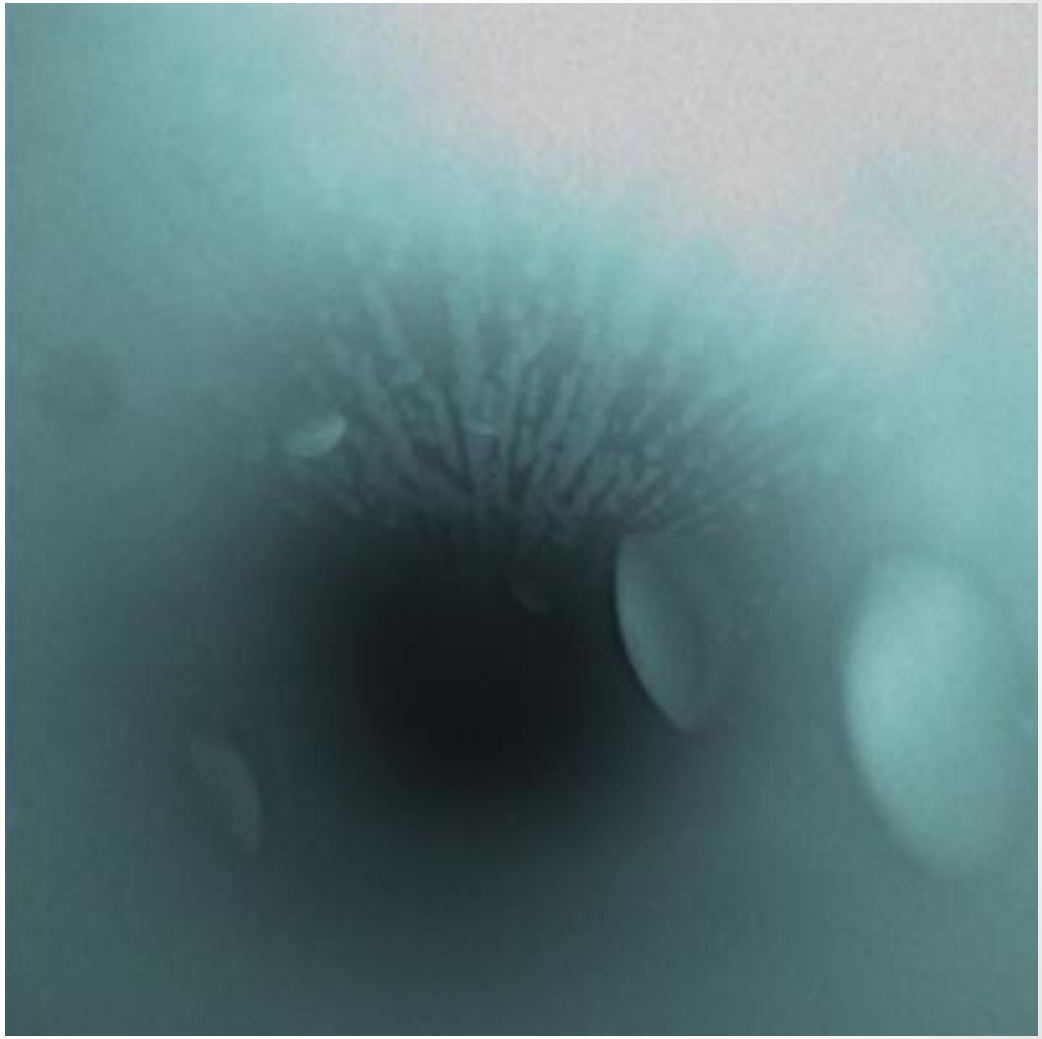
Debris inside a channel

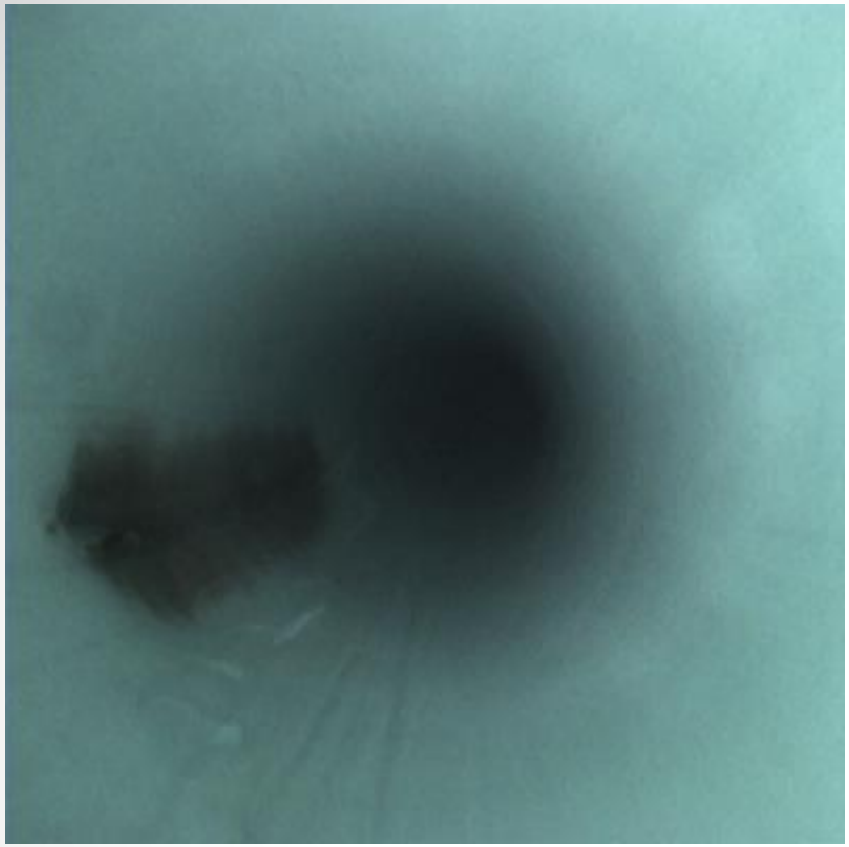


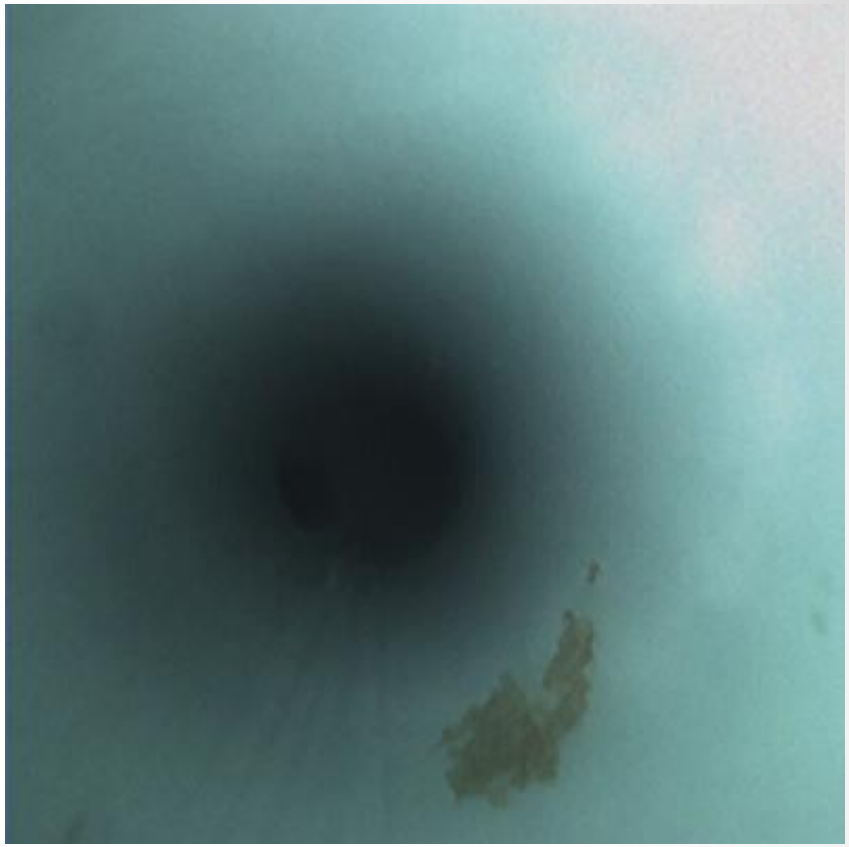


Shredding of the Channel

Moisture in the Channel







Staining and debris in channel

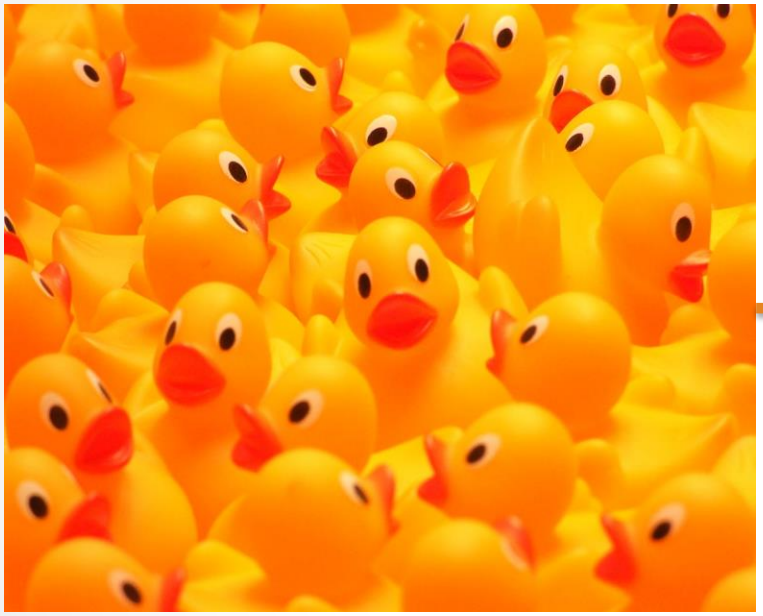
Visual Inspection Products

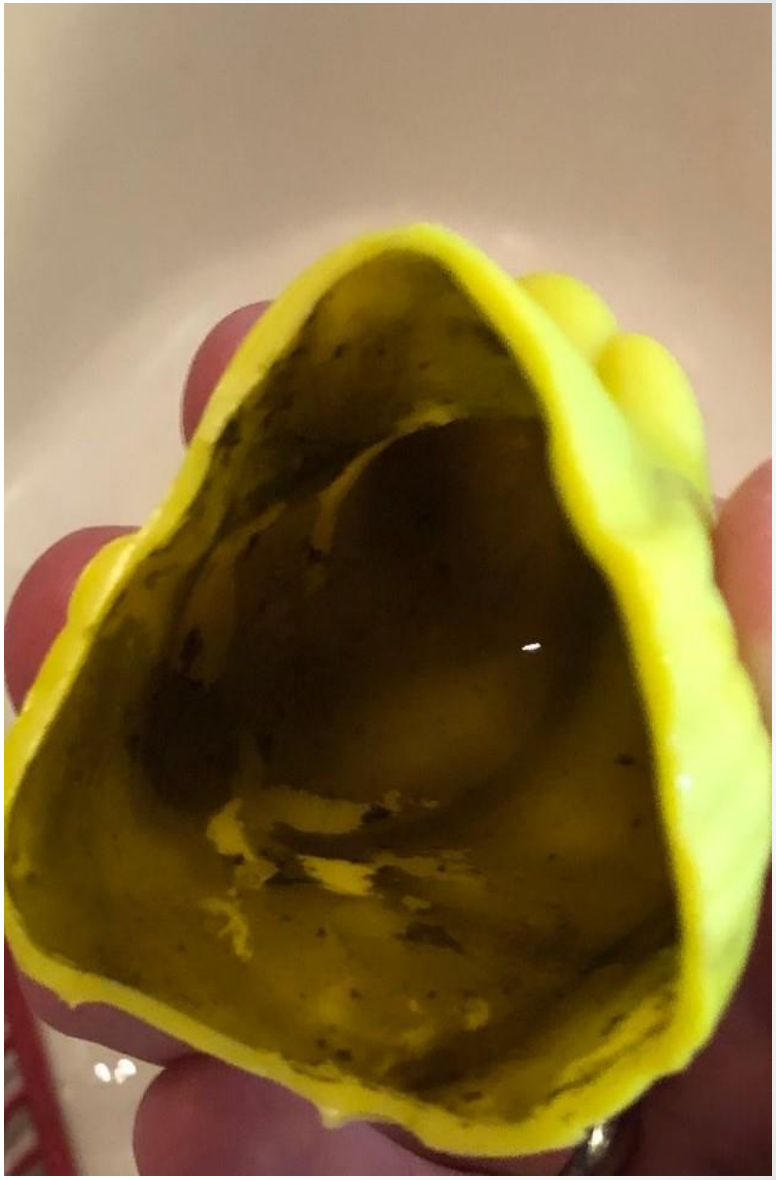
Helping you see where the naked eye cannot

Objectives

- Review best practices for manual cleaning of flexible endoscopes.
- Review rationale and current recommendations for cleaning verification.
- Identify the levels of inspection for flexible endoscopes and options to improve inspection through use of a borescope.

We need to inspect – including areas not easily seen





Stay alert and informed – you could be missing something important!

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Healthmark: https://www.hmark.com/

References – as noted on slides

Questions?

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