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Enhanced Visual Inspection of Flexible Endoscopes

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Manager of Clinical

Objectives

- Def ine visually clean and enhanced visual inspection for endoscopes
- Review the latest information from various organizations on enhanced visual inspection using a borescope
- Def ine best practices for enhanced visual inspection of medical devices

Overview of the 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

Inspection of Flexible Endoscopes

- CSA
- PHAC
- AAMI - ST 79 and ST 91
- AORN
- SGNA
- All support the practice of using some type of visual inspection to unaided eye

Basic visual inspection – Unaided Eye

- The most basic verif cation 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.
- Duodenoscope IFU:
  - Olympus 180 duodenoscope:
    - “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 f lushing 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.**

PHAC - 2011

- Equipment monitoring including visual inspection to identify conditions that may affect the cleaning or disinfecting process.
- During the manual cleaning process, trained personnel should inspect devices for functionality and damage.
- Visual inspections of equipment should be conducted to ensure that it is in proper working order in accordance with the endoscope manufacturer’s recommendations and to identify conditions that may affect the cleaning or disinfection processes.
- Visually inspect the scope to verify working properly.
- Source: PHAC 2011: Infection prevention and control guidelines for Flexible Gastrointestinal Endoscopy and Bronchoscopy

CSA – Decontamination of Medical Devices

- Remove damaged or defective scopes from service.
- Routine visual inspection and preventative maintenance of each endoscope provides valuable info about the scope's condition and can uncover the need for repair.
- Use of damaged or unclean endoscopes is a risk to patient safety.
- Identifying wear and tear, damage or deterioration is essential to good endoscope care.

CSA – Decontamination of Medical Devices

- A diligent inspection of the entire endoscopes shall be performed after each use shall include at minimum:
  - An overall assessment of the cosmetic appearance
  - No discoloration
  - No cracks
  - No sharp edges
  - No holes or other degradation

CSA – Decontamination of Medical Devices

- Insertion tub should be assessed to determine if the outer surface is damaged or punctured
- Distal end and cap should be round and smooth
- Lens at distal end or objective lens should not be cracked or dirty
- Biopsy channel recessed hole should be round, smooth and not impacted or cracked

CSA – Decontamination of Medical Devices

should be watertight

- If fluid is present after the disinfection process, the leak test should be re-done.
- If leak test is negative, then likely the cap is not water resistant

- The integrity of the cap should be assessed for missing, damaged or stretched o-rings
- Light guide connector prong should be checked to ensure that it is tight

CSA – Decontamination of Medical Devices

- Knobs should not be cracked, looks, leak or have a grinding feeling when turned.
- Endoscope should angulate smoothly without tightness or play
- Bending section should not bend irregularly
- Degree of angulations should be checked
  - Refer to scope IFU for angulation charts

US Guidelines - Enhanced Visual Inspection

- Inspection with **lighted magnif ication** supported by:
  - AAMI ST91: Inspection using magnif ication and additional illumination might identify residues more readily than the unaided eye
  - AORN: An endoscope that appears clean may harbor debris that cannot be seen without magnif ication.
    - Lighted magnif ication may increase the ability to identify residual soil

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 magnif cation 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.

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 **magnif cation** so all sections of the scope being cleaned can be well visualized.

- http://www.apic.org/Resource_/TinyMceFileManager/me

CDC Visual Inspection

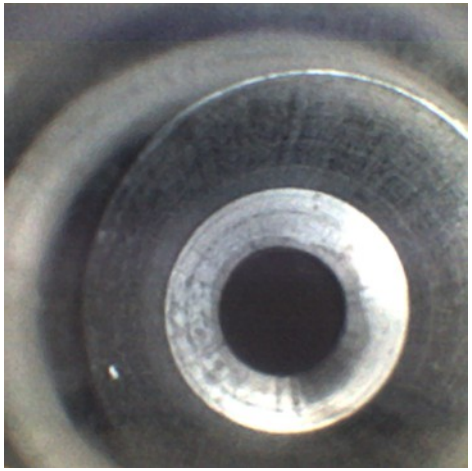
- Ensure that the elevator mechanism is thoroughly cleaned and free of all visible debris.
  - Visual inspection is to be done with the elevator in the “open/raised” position and “closed/lowered” position to ensure there is no visible debris above or below the elevator mechanism.
- Consideration should be given to use of a magnifying glass (e.g., 10x) to improve detection of residual debris around the elevator mechanism
- APIC: The IP will evaluate human factors, including ensuring that the cleaning area is set up with a **bright light** and **magnif ċation** so all sections of the scope being cleaned can be well visualized.

FDA on Visual Inspection

H. Visual Inspection - All routine cleaning instructions should include instructions for visual inspection, which may include use of magnif cation 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

- Not required in any endoscope IFUs at this time
- Suggested in the standards and guidelines
  - Tougher wording presently in draft standards
- Used in all major research papers (Healthmark FIS)



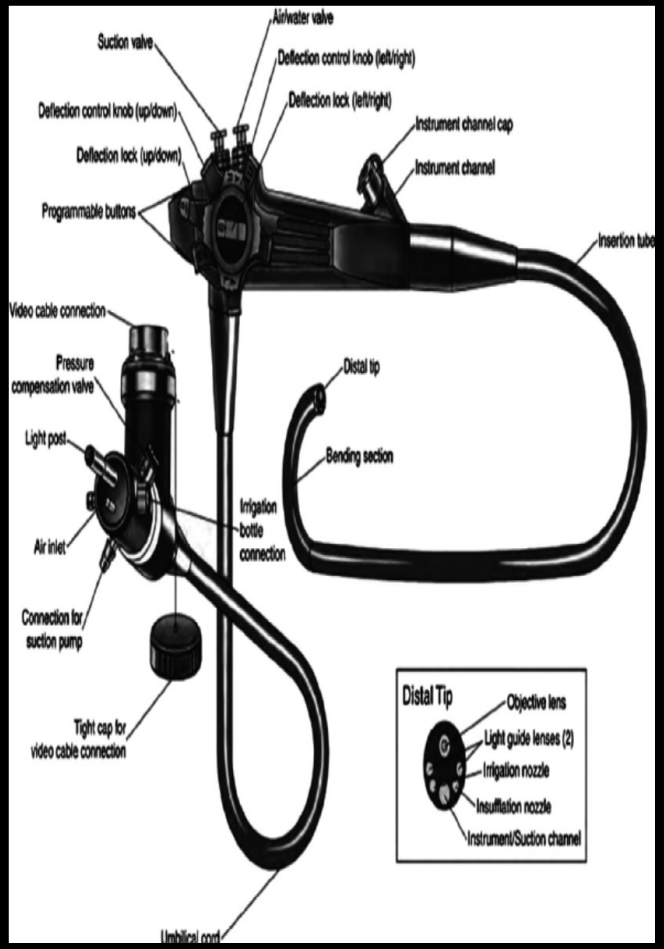
New biopsy area

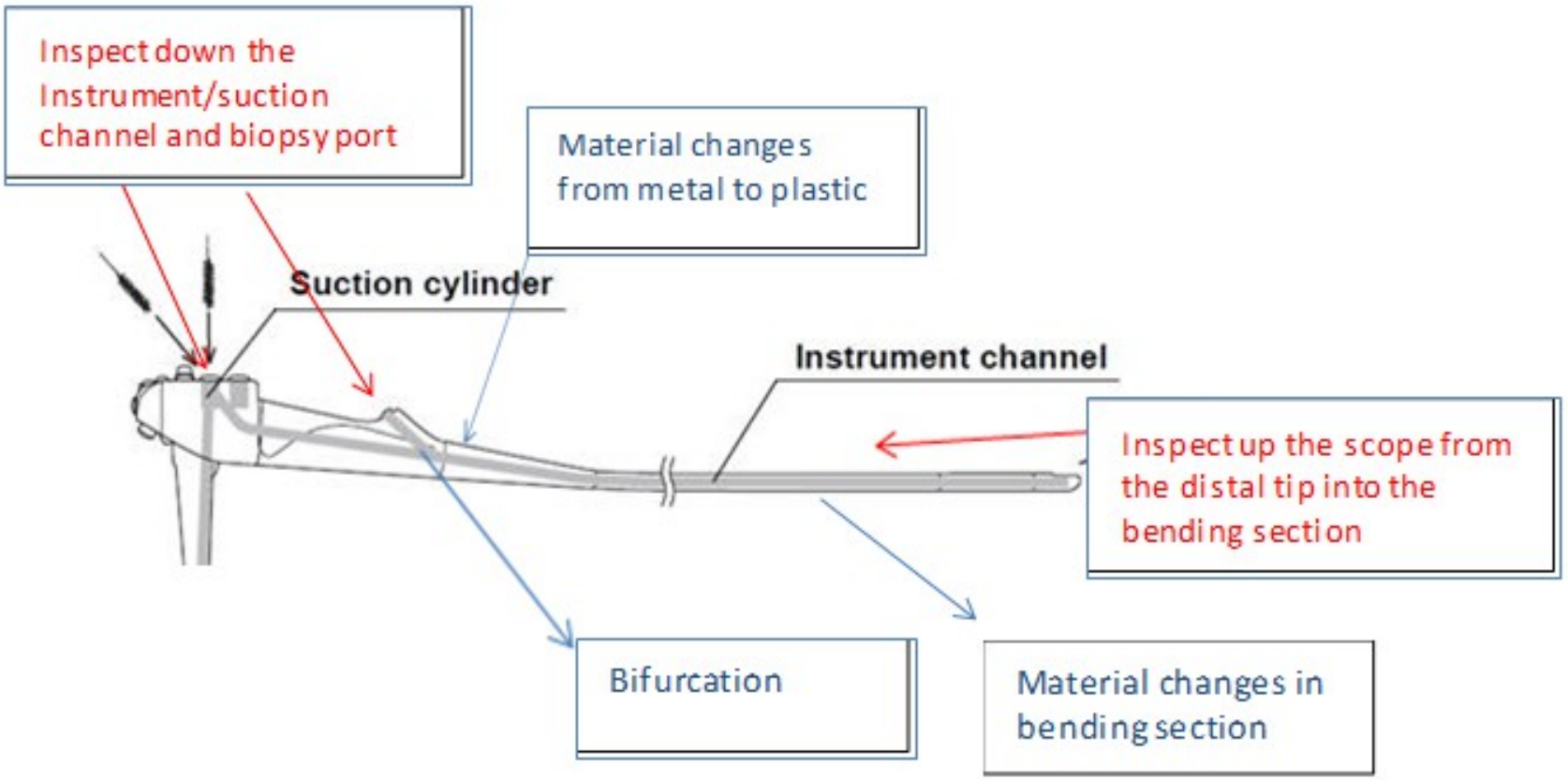
Inspection with a borescope

Inspection entails all of the scope

Where to inspect in a scope

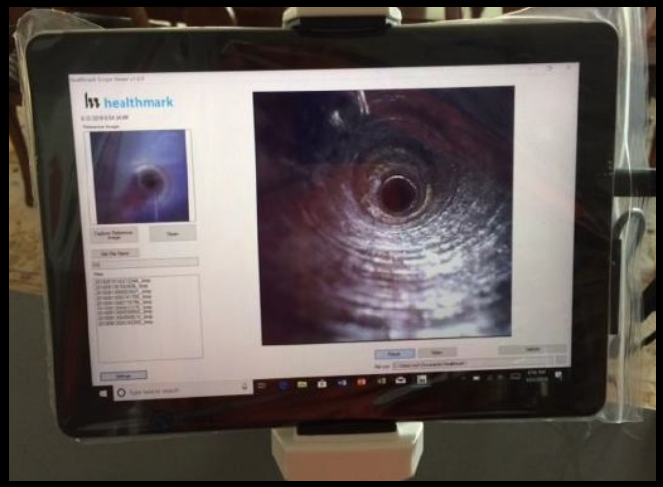
- Instrument/suction channel
- Valve openings
- Biopsy
- Distal tip
- Connection points within scope
- Forceps elevator
- Around control knobs
- Accessories




Inspect down the Instrument/suction channel and biopsy port
Material changes from metal to plastic
Suction cylinder
Instrument channel
Inspect up the scope from the distal tip into the bending section
Bifurcation
Material changes in bending section

When to inspect with a borescope?

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



When to inspect with a borescope

- After manual cleaning 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.

When to inspect with a borescope

- After disinfection and 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!

Borescope Information

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

Supporting research and documents

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

HOW TO GET TO VISUALLY CLEAN | **SITE & SURFACE INSPECTION**

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BACKGROUND

Visual inspection is the most often specified technique for inspecting medical devices. Standards, guidelines and articles all support the use of visual aids and tests for stain identification to ensure medical devices are clean and functional before they are high level disinfected or sterilized and then ultimately used on a patient.

"...inspection should be done just prior to sterilization. Inspect all instrument surfaces and individual parts for: Cleanliness of instruments, i.e. no debris, blood, tissue, etc. If not fully clean, repeat previous cleaning steps or properly dispose of the instruments..."[1]

"...After cleaning, visually inspect all surfaces, ratchets, box locks, holes, channels and lumens for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination..."[1]

"Visual inspection is defined as the process of using the unaided eye, alone or in conjunction with various aids, as the sensing mechanism from which judgments may be made about the condition of a unit to be inspected."[1]

"...visually inspect the hand piece, including all internal surfaces, for remaining soil. Use an endoscopic camera and endoscope if necessary to see the inner surface of the lumen. If soil remains, repeat the manual cleaning procedure, focusing on those areas..."[1]

"...If areas are difficult to inspect visually, check for blood by immersing or flushing the device in a 3% hydrogen peroxide solution. If bubbling is observed, blood is present. Rinse devices thoroughly after using hydrogen peroxide solution. If soil is still present, re-clean the device..."[1]

"... A stain is a discoloration on an instrument's surface. Rust is a red or orange coloration on the surface of surgical instruments resulting from oxidation. Note: Ensure that a "stain" observed is not dried blood... Use the eraser test to check for rust by rubbing an eraser over the stain/rust. If the spot is easily removed, it is a simple stain. If you discover pitting under the stain, it cannot be repaired..."[1]

"Inspection using enhanced visualization tools such as lighted magnification and video borescopes might identify residues not observable by the unaided eye"[1]

"...Inspection using magnification and additional illumination might identify residues more readily than the unaided eye... tools such as video borescopes of an appropriate dimension (length and diameter) may be used to visually inspect the internal channels of some medical devices..."[1]

"...protein is a marker commonly used to evaluate cleaning efficacy... health care personnel inspect every device for visible organic soil and contamination in a simple functionality check, usually as part of the inspection, preparation, and packaging procedure..."[1]

So, what is visually clean and what are the steps a medical device reprocessing professional should take to ensure a medical device is visually clean? It is a simple process of site and surface inspection that must be performed each time a medical device is handled.

Visual inspection is a process of using the unaided eye, alone or in conjunction with various aids (borescope, magnifier, stain identification) to inspect medical devices for defects in functionality, pitting, stains, and imperfections during its processing cycle and rejecting the medical device according to the medical devices IFU if any imperfections are found. Stain identification is a process of using various methods to detect what the makeup of that stain is, and correct it from appearing again.

The standard, "is the medical device visually clean?" and understanding the type and source of the stain helps you reduce the chance of it reoccurring again in your process.

First, if it is visually dirty, you must re-clean it (unaided eye detection).

Second, visually inspect with the use of a magnifying glass.

Third, use enhanced visual inspection (Borescope, Flexible Inspection Scope, USB microscope); consider hard to see areas of a medical device, like a lumen.

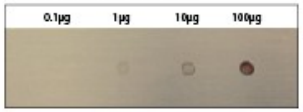
Fourth, stain identification. You want to know what the stain is composed of (rust, organic soil, blood, protein, or another bioburden). Then, work towards resolving the issue to prevent it from appearing again.

DISCUSSION

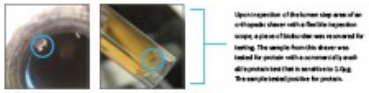
Who is telling medical device reprocessing professionals to visually inspect instruments? The manufacturer of the instruments with their IFU (Instructions For Use) then the standards, guidelines, articles and studies, and lastly, the customer, who is the patient. They want a clean and functional medical device. The facility must decide what medical devices should be inspected, how often, and with what. Deciding how to reach "visually clean" can only be accomplished with research (risk or gap analysis) into the specific issues of that facility. Researching these solutions should be done as a team made up of medical device reprocessing professionals, risk management, infection control and other key members of the facility.

STAIN COLOR	POSSIBLE CAUSE
BROWN/ORANGE	HIGH pH OF CLEANING SOLUTION
GRAY	EXCESSIVE USE OF RUST REMOVER
BLACK/PURPLISH	CONTACT WITH AMMONIA
LIGHT/DARK COLORED SPOTS	WATER DROPLETS DRYING ON THE SURFACE

STAINS OF PROTEIN ON STAINLESS STEEL



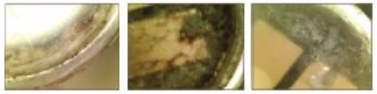
EXAMPLES OF DEBRIS FOUND IN SHAVERS AFTER CLEANING



Upon inspection of the lumen step area of an orthopedic shaver with a flexible inspection scope, a piece of black debris was recovered for testing. The sample from this shaver was tested for protein with a commercially available protein test that is sensitive to 1.0µg. The sample tested positive for protein.

Actual scraping/peeling of the inner lumen of an endoscope found during inspection after the cleaning process. This needs to be sent back for repair. This could dislodge and go into a patient during examination.

DEBRIS FOUND IN DOPPLER PROBE TIPS USING A USB MICROSCOPE



STAINS THAT COULD BE MISTAKEN FOR HARD WATER SPOTS, TESTED POSITIVE FOR HEMOGLOBIN

SOLUTIONS

Who is telling medical device reprocessing professionals to visually inspect instruments? The manufacturer of the instruments with their IFU (Instructions For Use) then the standards, guidelines, articles and studies, and lastly, the customer, who is the patient. They want a clean and functional medical device. The facility must decide what medical devices should be inspected, how often, and with what. Deciding how to reach "visually clean" can only be accomplished with research (risk or gap analysis) into the specific issues of that facility. Researching these solutions should be done as a team made up of medical device reprocessing professionals, risk management, infection control and other key members of the facility.

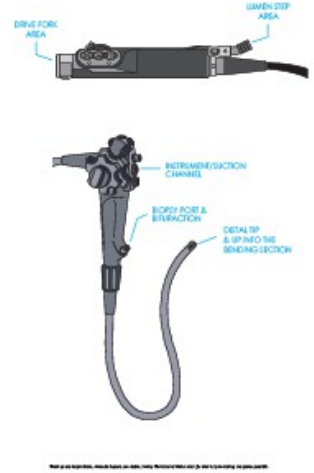
EXAMPLES OF ENHANCED OPTICAL INSPECTION TOOLS

EXAMPLES OF SURFACE TEST METHODS

Surface hemoglobin test:
This swab method produces a colorimetric result that is easy to interpret. Sensitive down to 0.1µg hemoglobin.

Surface protein test:
This swab method produces a colorimetric result that is easy to interpret. Works for both soluble and insoluble proteins; detection limit of 1.0µg within minutes.

KEY AREAS TO EXAMINE WITH A FLEXIBLE INSPECTION SCOPE THAT THE UNAIDED EYE CANNOT SEE [1]



A SAMPLE FLOW CHART FOR A MEDICAL DEVICE REPROCESSING DEPARTMENT

Support for using enhanced visual inspection – Poster at AORN 2017

Multisite study on ureteroscope reprocessing effectiveness

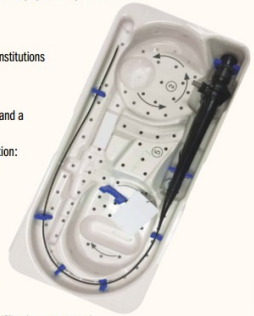
Cori L. Ofstead, MSPH[1]; John E. Eiland, RN, MS[1]; Otis L. Heymann, BA[1]; Mariah R. Quick, MPH[1]; Harry P. Wetzler, MD, MSPH[1]
[1]Ofstead & Associates, Inc., Saint Paul, MN, USA

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

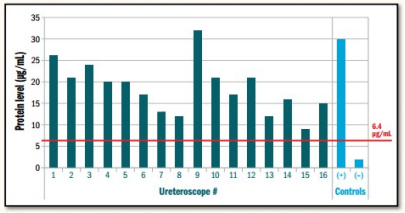
- Flexible ureteroscope characteristics (N=17):
  - Average age 2.1 years
  - Repairs required after an average of 19 uses due to:
    - Failed leak tests
    - Inadequate image quality
    - Broken fibers
    - Pinched insertion tubes
- Reprocessing involved:
  - Manual cleaning by reprocessing technicians
  - 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

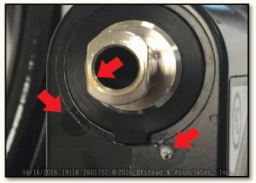
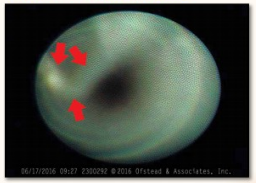


Photo 2. Scratches and gouges surrounding channel port

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.

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7. Storms L. Olympus Urgent Medical Device Safety Notice; 2016.

http://www.ofsteadinsights.com/?p=2303

Support for using enhanced visual inspection – Poster at

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]

[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

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

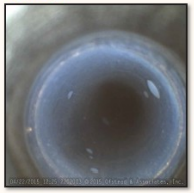


Photo 2. Fluid inside the suction/biopsy channel of a colonoscope

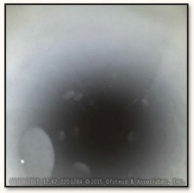


Photo 3. Irregular surfaces and brown staining inside the distal end of a colonoscope

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

Figure 1. ATP test results after manual cleaning

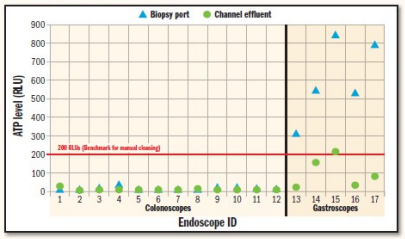
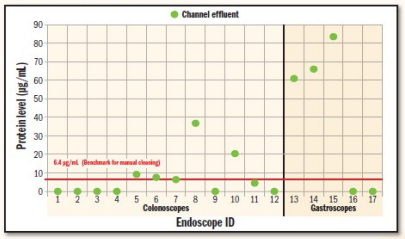


Figure 2. Protein test results after manual cleaning



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.

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1. Epstein L, et al. *JAMA*. 2014;312(14):1447-1455.
2. Wendorf KA, et al. *ICHE*. 2015;36(6):634-642.
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.
5. Verfaillie CJ, et al. *Endoscopy*. 2015;47(6):493-502.

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Poster at SGNA 2016

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

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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

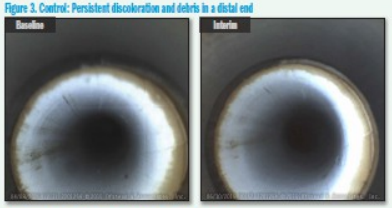


Figure 2. Residual fluid in a channel

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

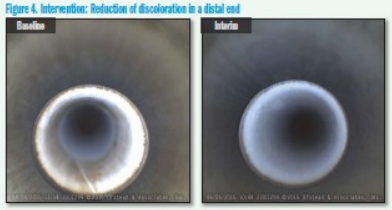
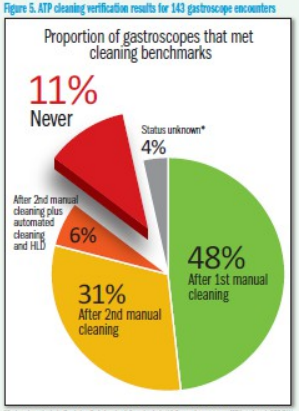


Figure 5. ATP cleaning verification results for 143 gastroscope encounters



*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

1. Bajolet O. J Hosp Infect. 2013;83(4):341-343.
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3. England D. ICHE. 2016:1-2.
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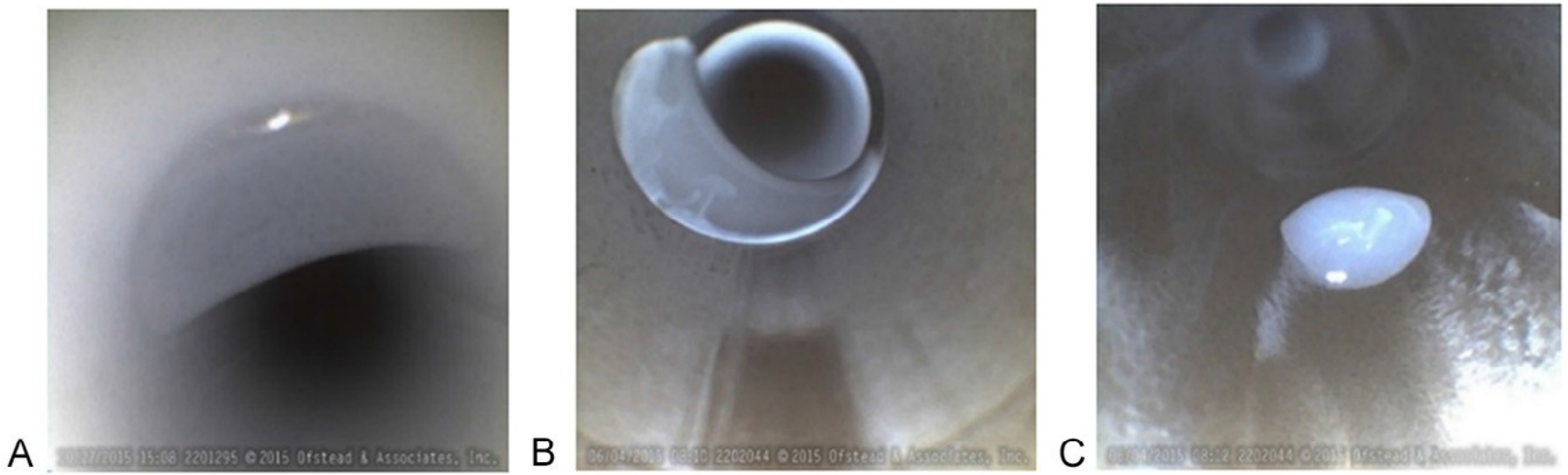
Support for using enhanced visual inspection



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

Support for using enhanced visual inspection

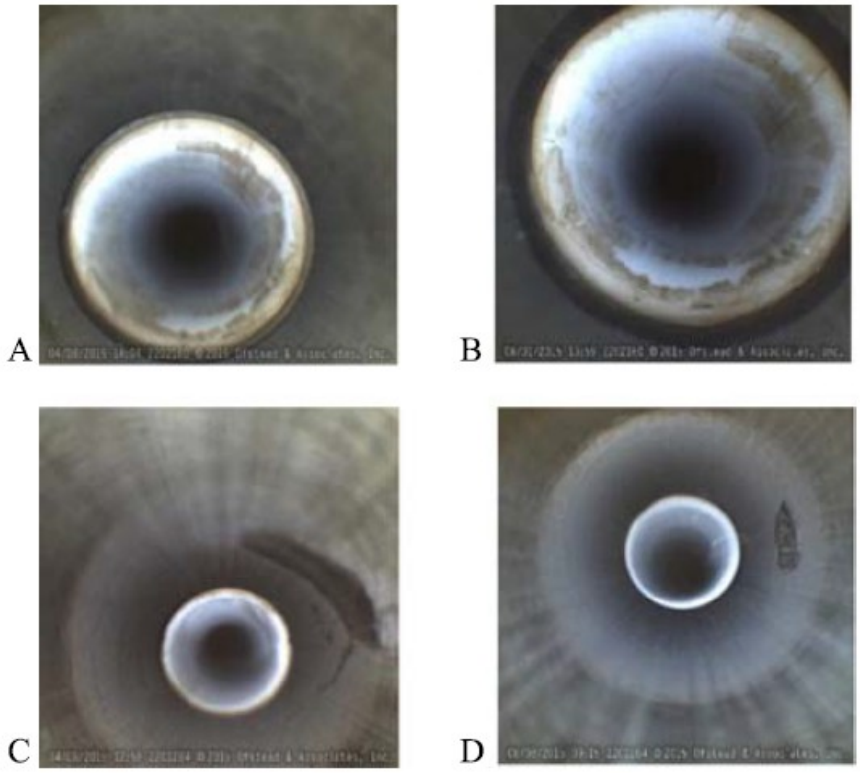


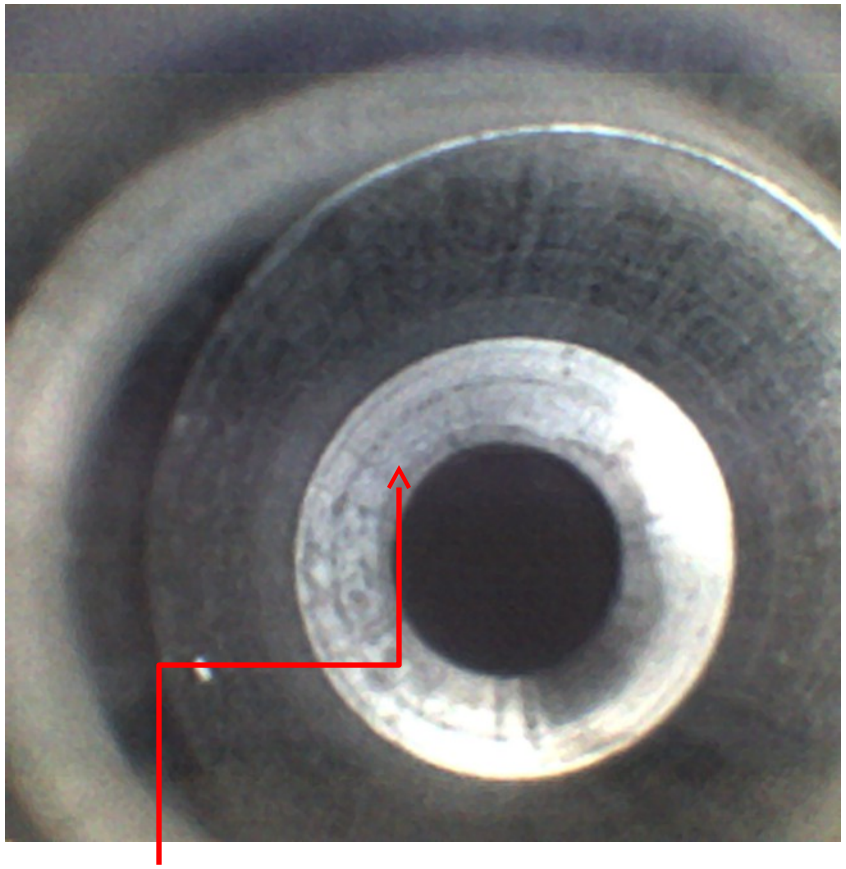
Fig 2. Discoloration and scratches observed. (A) In a control group colonoscope at baseline. (B) In the same control group colonoscope at 2-month assessment. (C) In an intervention colonoscope at baseline. (D) In the same intervention colonoscope at 2-month assessment.

- Borescope inspection identified scratches, discoloration, debris, & fluid
- These changed over time
- Allowed damaged and contaminated scopes to be identified and reprocessed and sent for repair
- When went for repair, manufacturer determined

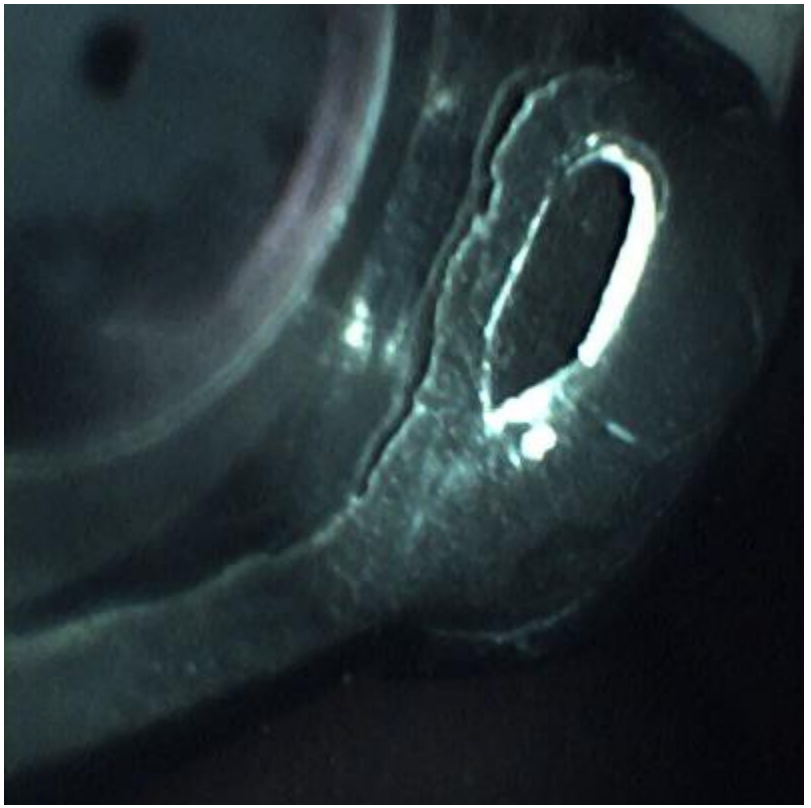
- Reference; Ofstead and associates, AJIC, 2016, Article in press

Photos taken with a borescope

Borescope Examination Showing a Cracked Water Jet

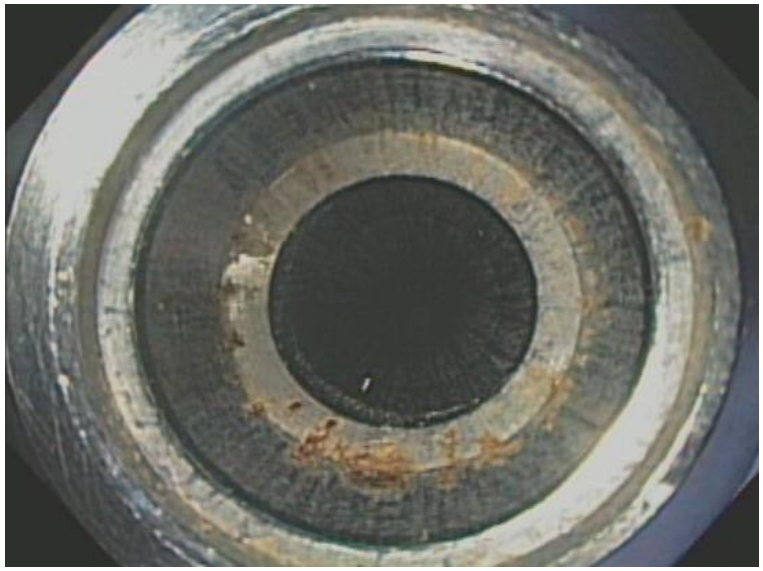


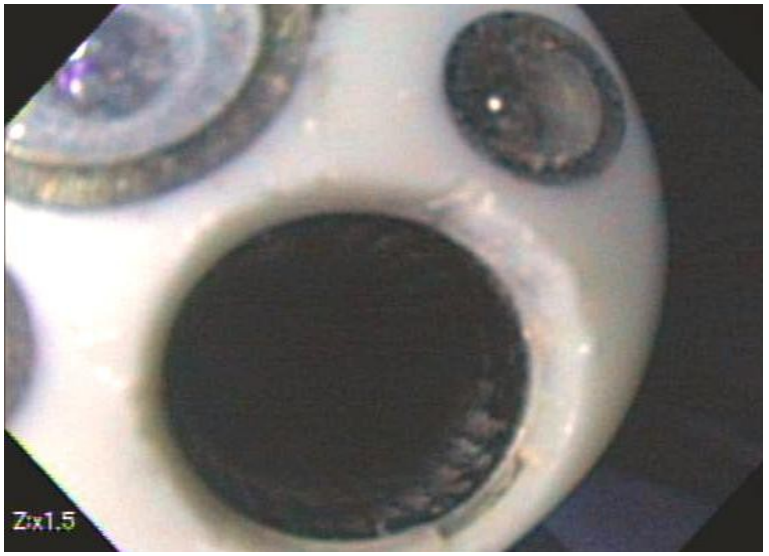
The crack in the weld at the water jet nozzle not picked up by a leak test

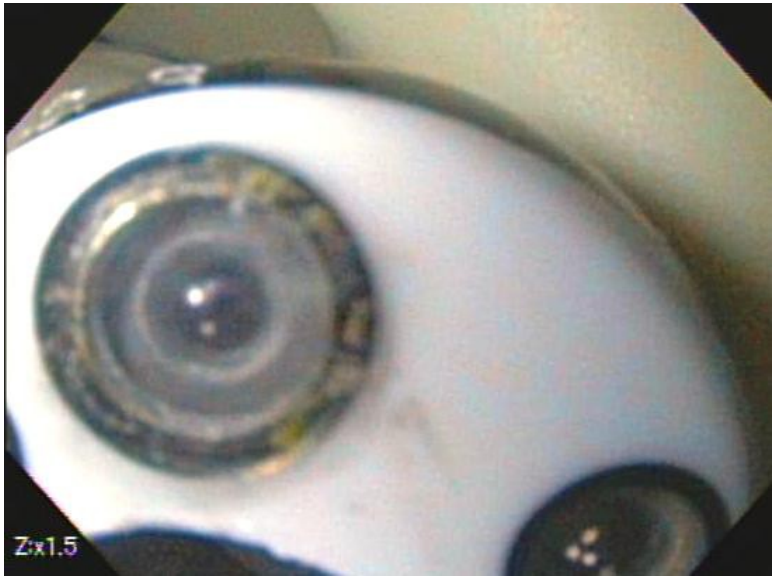


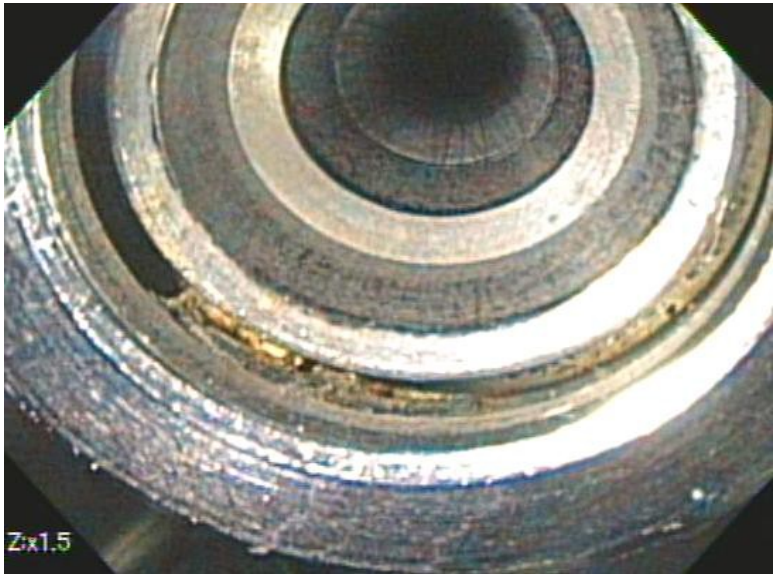
Inside a biopsy port channel of an endoscope

Examples of Debris and Damage Found in Endoscopes.

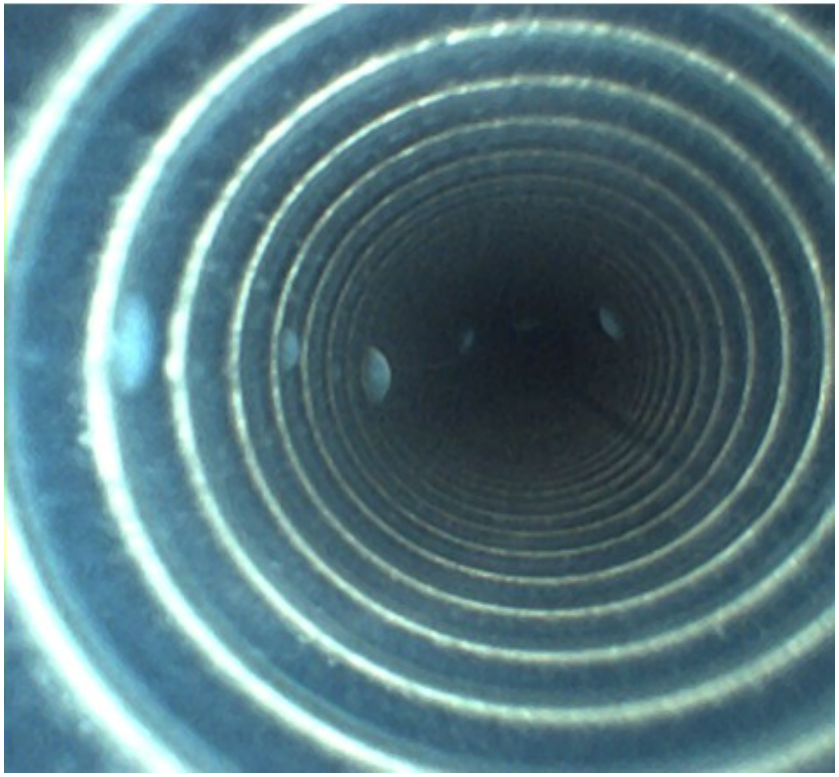




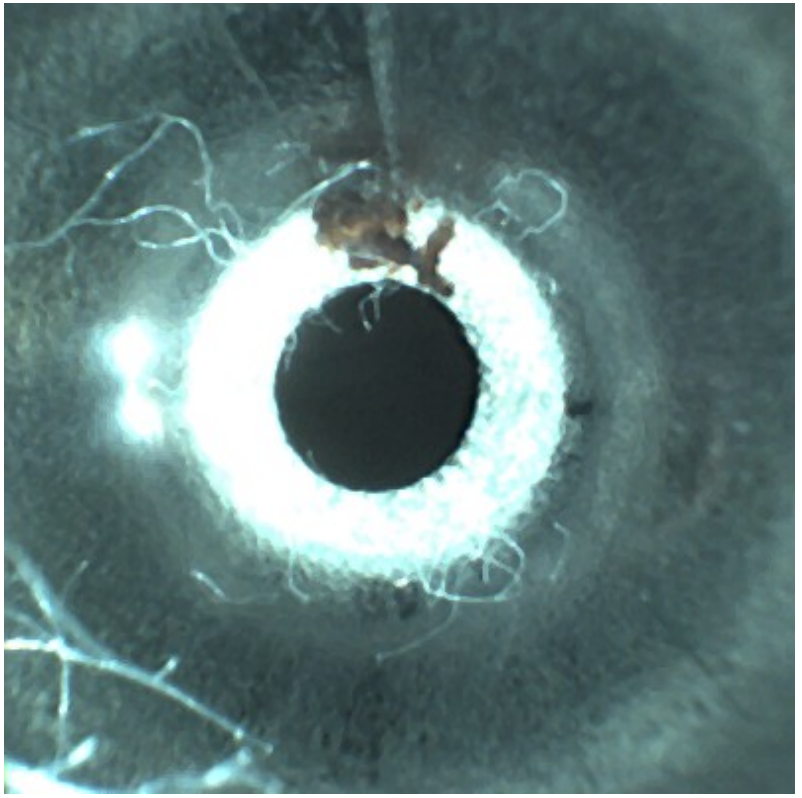




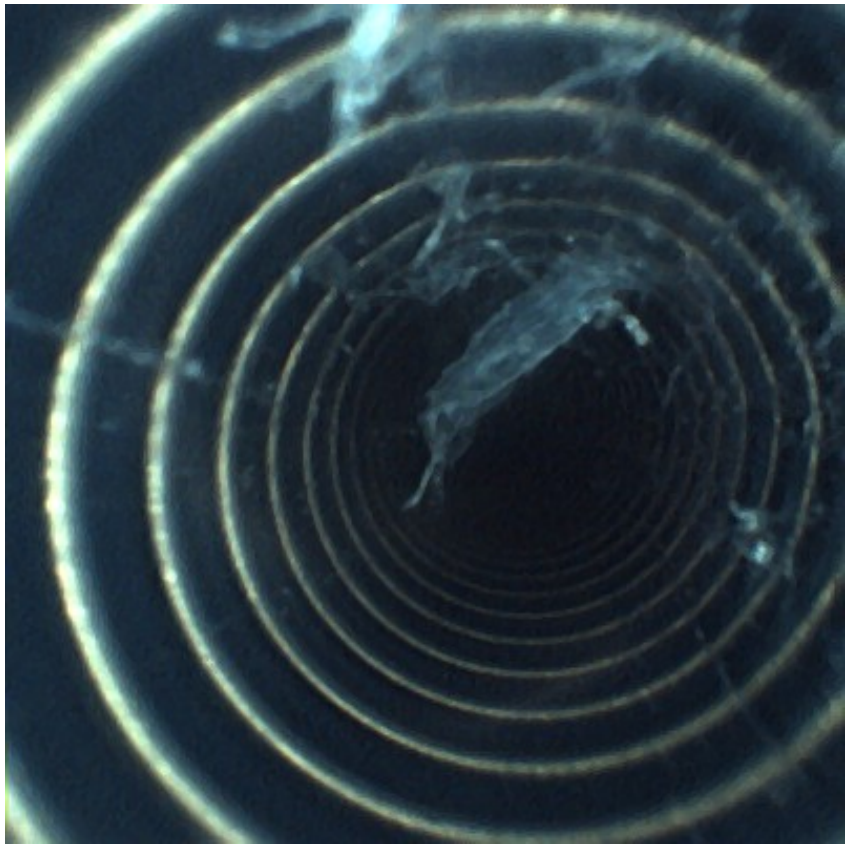
Borescope Examination Photos using the FIS

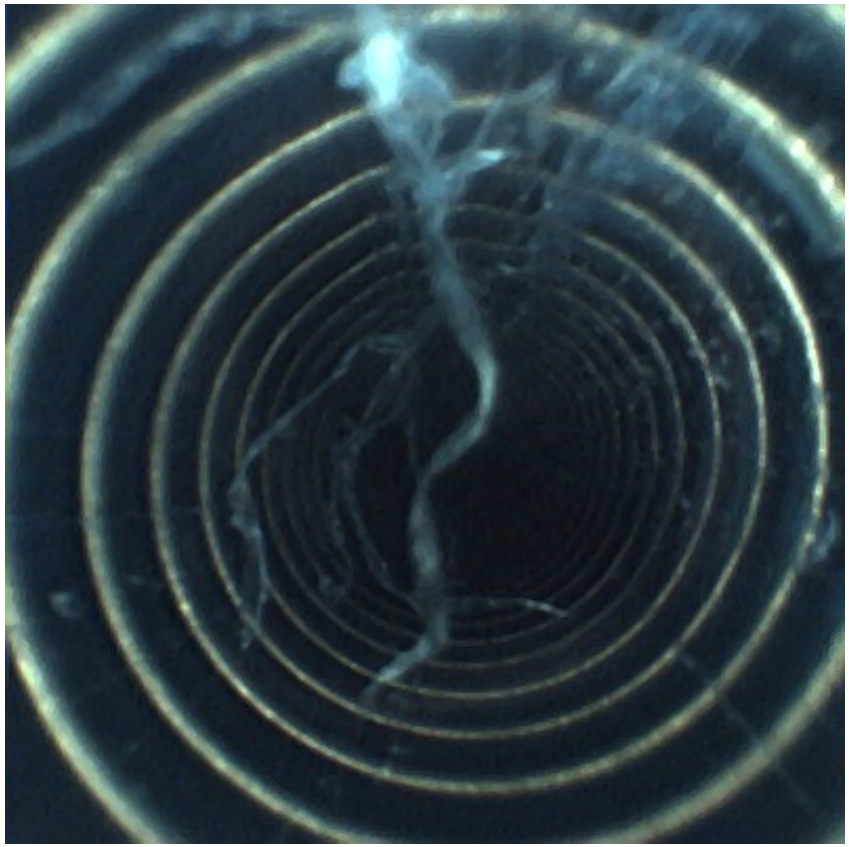


Fluid in Channel of “DRY” scope



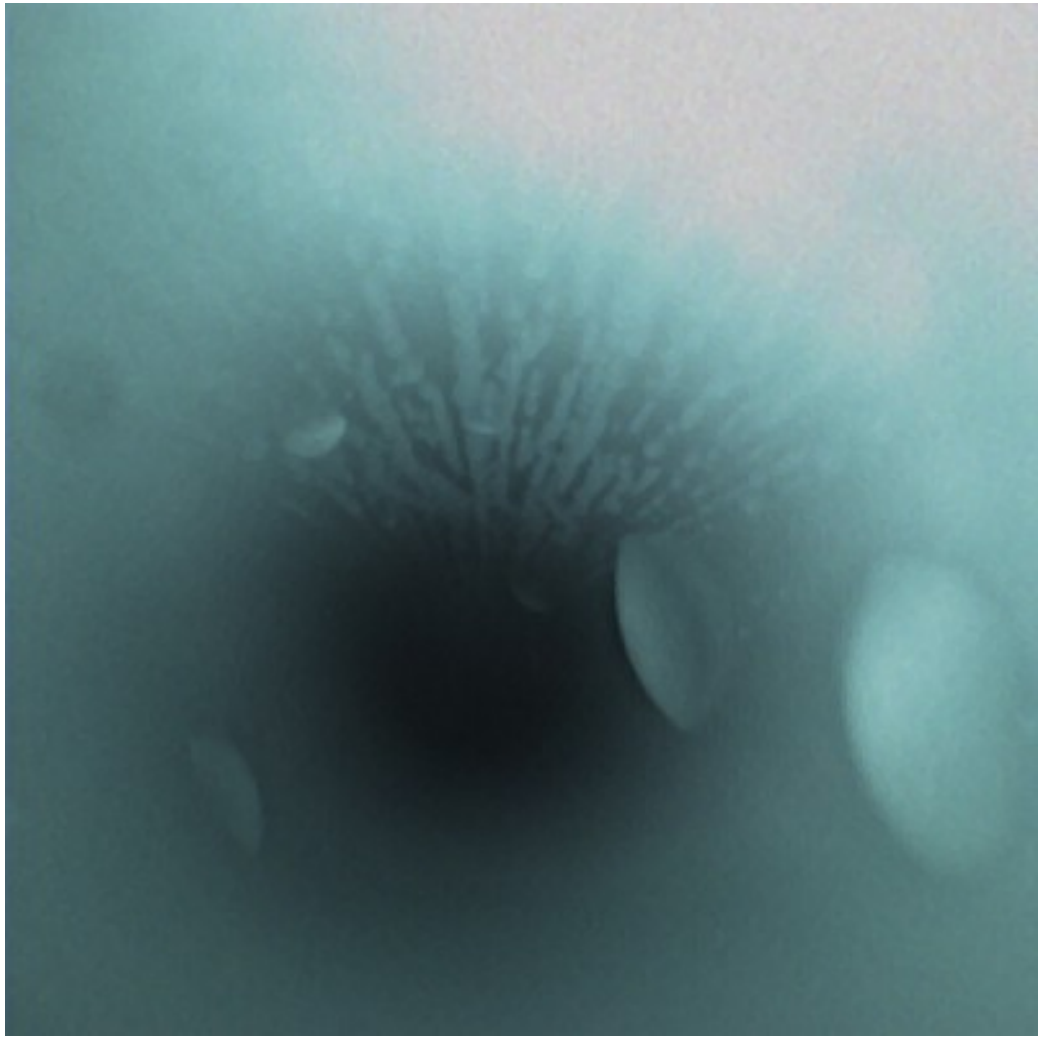
Debris inside a channel

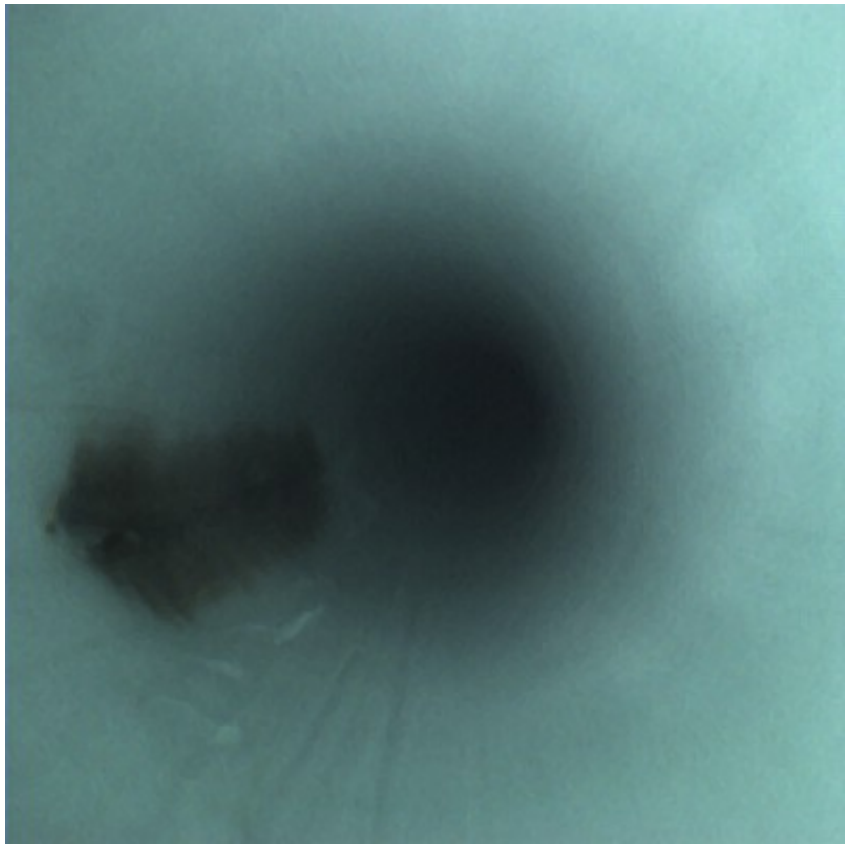


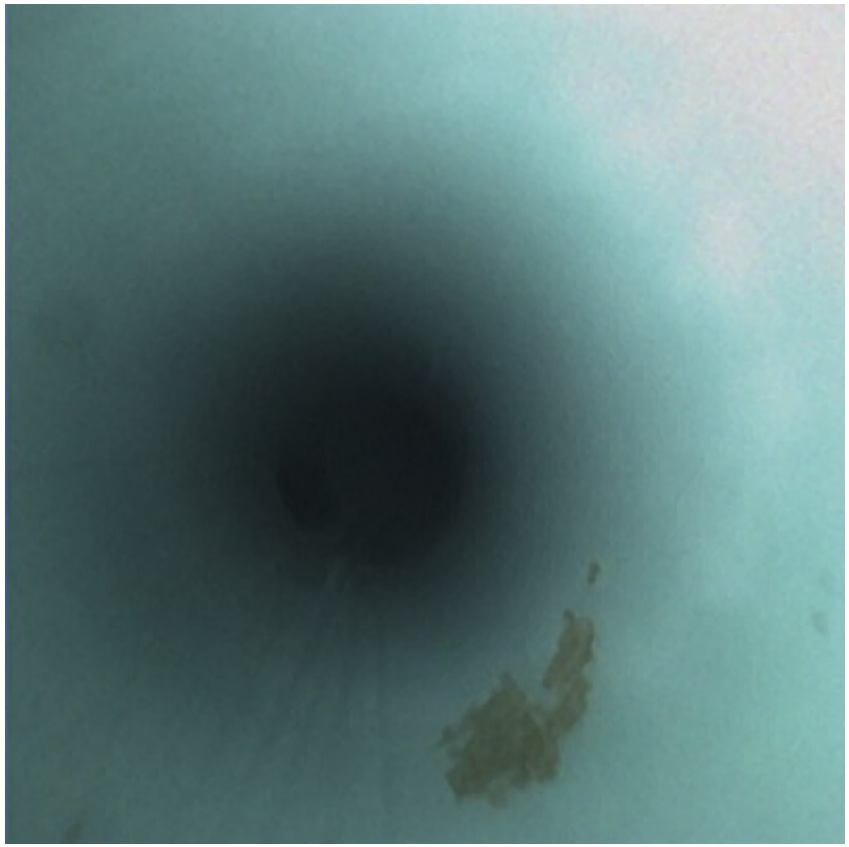


Shredding of the Channel

Moisture in the Channel







Staining and debris in channel

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- Thank you! Questions?