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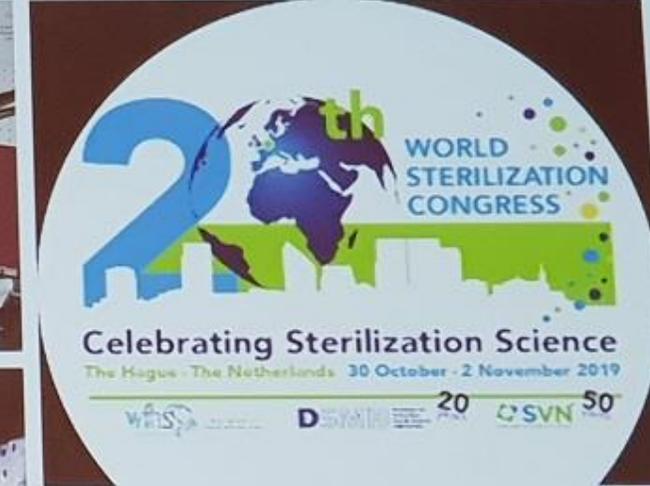
to the 20<sup>th</sup> World Sterilization Congress



# Redefining Visual Inspection for Medical Devices

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# 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).

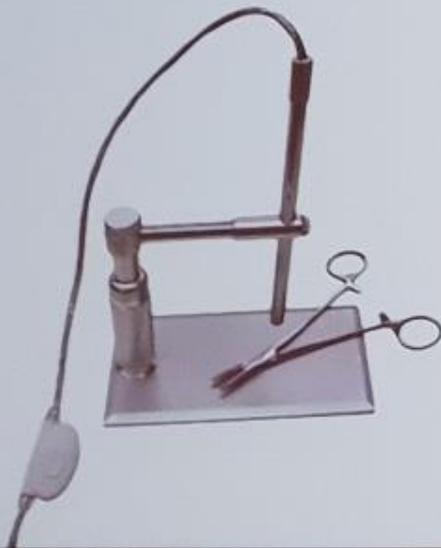
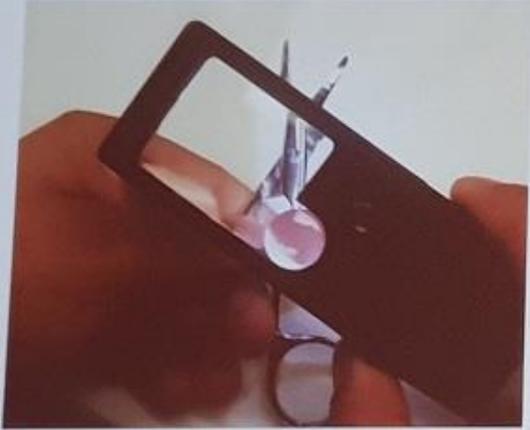
# Objectives

- Define visual inspection
- Explore the evolution of visually inspection of medical devices with the naked eye to the present-day enhanced visual inspection tools (borescope).
- Review what the standards, literature, and other information say on all types of visual inspection, especially borescope inspection.
- Show with pictures why enhanced visual inspection with a flexible inspection scope (borescope) is needed in medical device reprocessing departments.
- The Rabbit Hole Theory

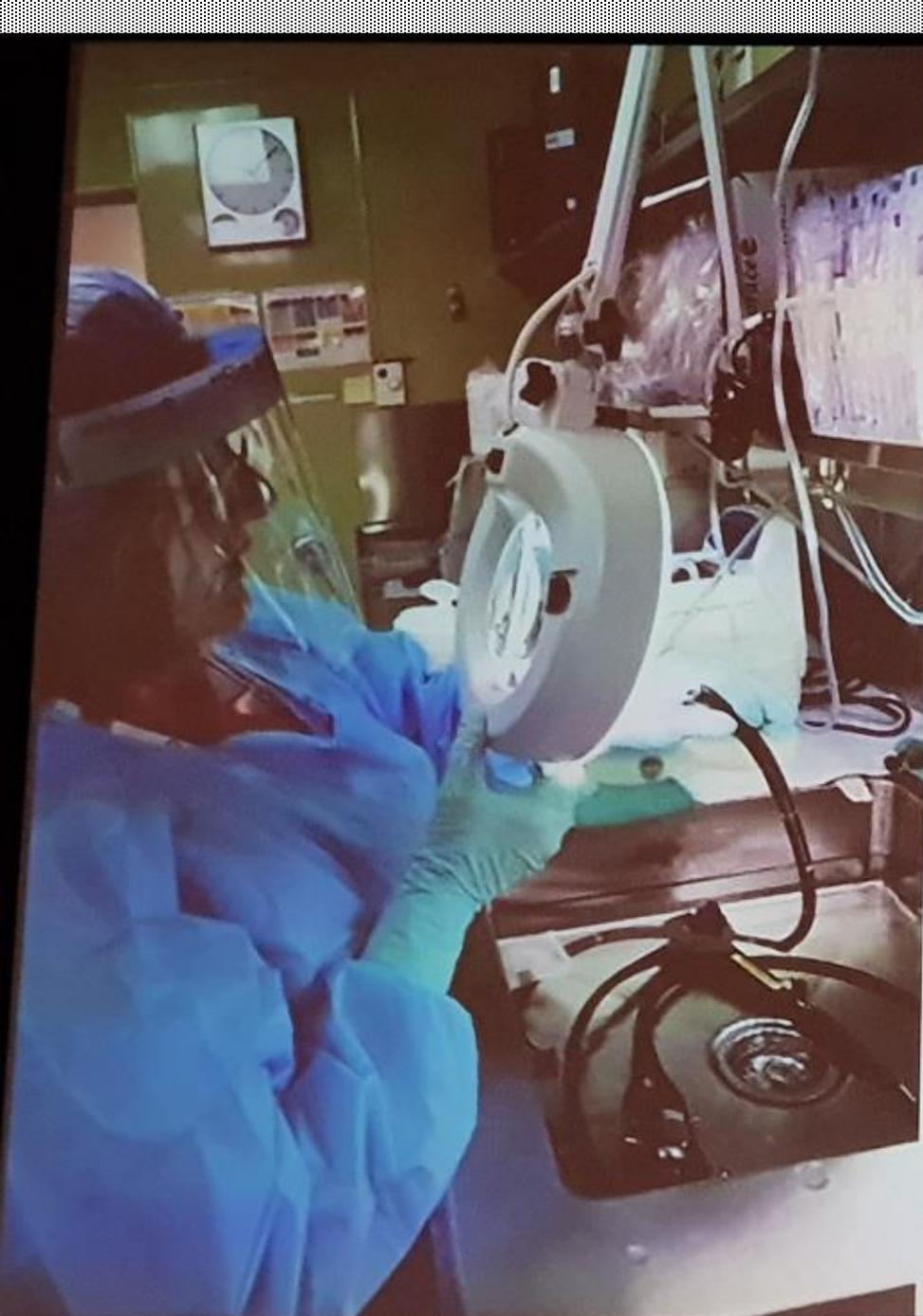


***“We cannot force someone to hear a message they are not ready to receive. But we must never underestimate the power of planting a seed.”***

# Foundation of Understanding



- First, the standard “Is it visually clean and functional?”
  - Unaided eye
  - If it is visually dirty, you must re-clean it
  - Examine the device (inspect)
    - External surface
    - Internal surface
  - Is it damaged/functional?
  - This takes place at the same time
- Second, some form of enhanced visual inspection
  - The IFU gives us direction
  - Standards and guidelines
  - Training manuals
    - Magnifying glass
    - Borescope
    - Computer/digital
    - Microscope
    - Others



# Objective 1: Define Optical Inspection

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Optical inspection is defined as the process of **using the unaided eye, alone or in conjunction with various aids (enhanced)**, as the sensing mechanism from which judgments (inspection) may be made about the condition of any medical device to be inspected.

- Duodenoscope IFU Olympus:
  - 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 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**”.

## Borescope Inspection – Enhanced Visual Inspection

- Borescopes (flexible inspection scope) enter device lumens and allow for direct visual inspection
  - Shavers
  - Endoscopes
  - Suctions
  - Other lumen devices



## Objective 2:

- Explore the evolution of visual inspection of medical devices with the naked eye to the present-day enhanced visual inspection tools (borescope).
  - Basic external surface
    - Naked eye vs. basic magnification
    - Naked eye vs. digital
- Every time we pick up any medical device, we are always looking at it with our unaided eye inspecting for pits, cracks, bent tips, misalignment, corrosion, etc.
- If we see something and we have some type of magnification available, we use it to explore deeper and see if the medical device is clean and functional (damaged).

# The First CSSD 400BC & The Start of Visual Inspection of Medical Devices

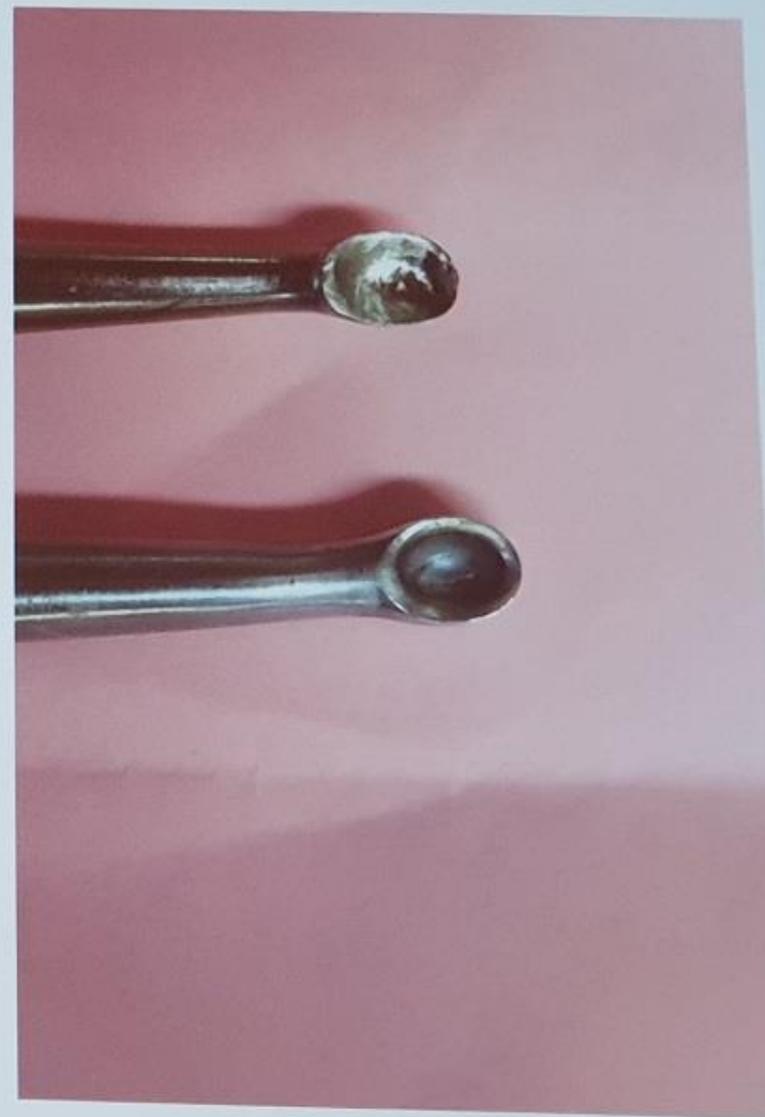


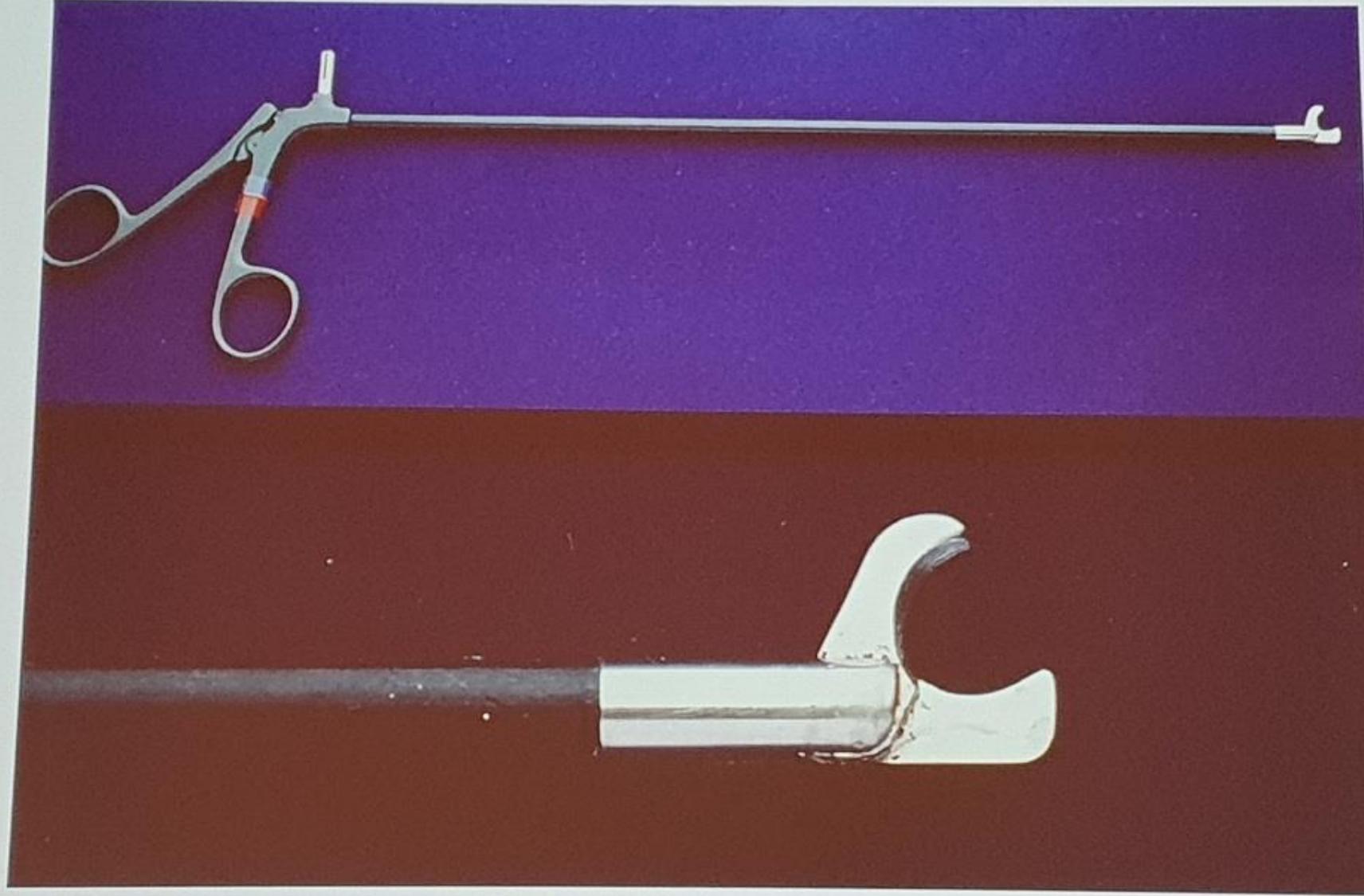
CSSD (Really Surgery) - Hippocrates. 400 B.C.E.  
The things relating to surgery, are the patient; the operator; the assistants; the instruments; the light, where and how; how many things, and how; where the body, and the instruments; the time; the manner; the place..the instruments, and when and how they should be **prepared, will be treated of afterwards; so that they may not impede the work**, and that there may be no difficulty in taking hold of them, with the part of the body which operates. But if another gives them, he must be ready a little beforehand, and do as you direct.

They had to look at the instruments with the unaided eye - visual inspection was being used.



Unaided Eye  
vs.  
Magnified





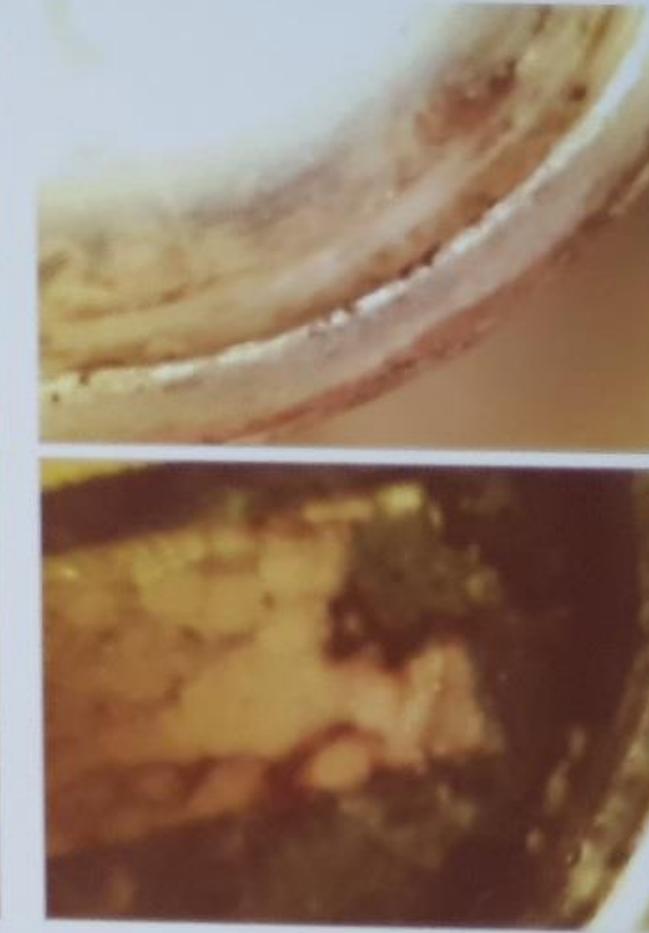
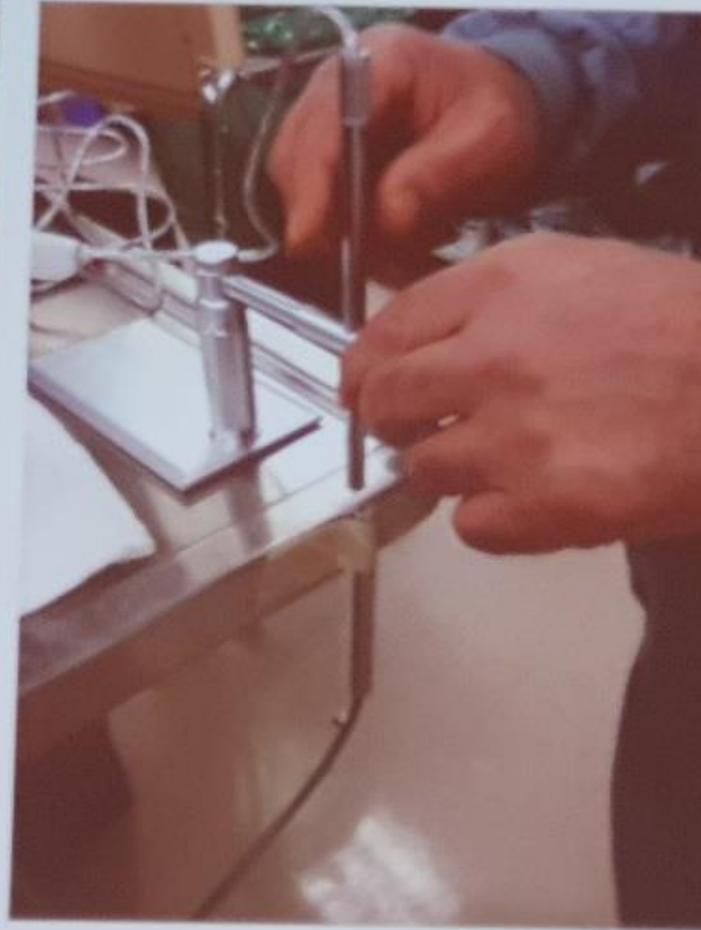
Unaided Eye vs. Magnified



To the naked eye, this crack appeared to be only a small scratch in the finish of the instrument. However, upon closer examination this critical failure in the instrument integrity was found.

*“Visual inspection of surgical instruments following decontamination is a universal requirement for surgical instrument reprocessing. Despite the ubiquity of the practice, visual inspection technology has been slow to move into the digital age. In most sterile processing departments lighted desktop magnifying lenses are a common sight. However, the time has come for sterile processing departments to adopt better technology in order to give their technicians the best possible resources to keep patients safe”*

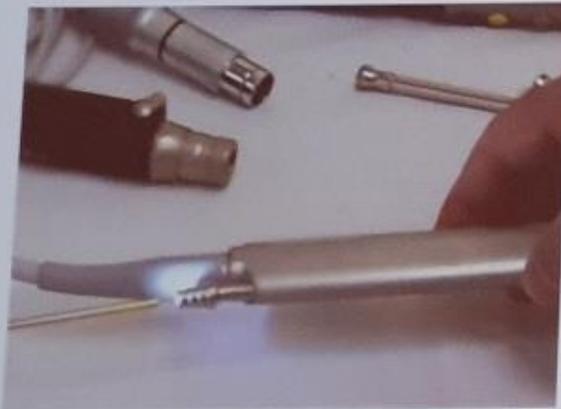
<https://hpnonline.com/new-age-visual-inspection/>



Doppler Probe Tips inspected after cleaning with an unaided eye vs. USB Microscope. These tips were positive for blood residue when tested.

# How did we get to need enhanced visual inspection ?

## CSSD/SPD/CPD/MDRD had a Shaver Issue in 2009 - Timeline



- Visual Inspection takes place every time we touch an instrument
- BECAUSE WE ARE IN A DYNAMIC ENVIRONMENT, CHANGE IS CONSTANT
- Medical devices are becoming more complex
- The FDA has become aware of events in which tissue has remained within certain arthroscopic shavers, even after the cleaning process was believed to have been completed according to the manufacturer's instructions (April 2009).
- Reports submitted to the FDA suggested that the tissue retained was not evident to the naked eye.
- FDA issues an Alert to manufactures of shavers to inform customers of issues of retained tissue...FDA encouraged facilities that use arthroscopic shavers to consider inspecting the inside of these devices (eg, with a 3-mm video scope) after cleaning to ensure that they have been cleared of any tissue or fluids.
- Multiple manufacturers of these devices informed their customers of this situation and reiterated the importance of proper cleaning procedures. The need for enhanced inspection, proper brushes....
- Healthmark begins the process to develop the first Flexible Inspection Scope ( borescope) for medical devices that have lumens / channels with Jahan Azzi at the University of Michigan in the fall of 2009. Product introduced in 2011.
- Present Day , the need has been justified for this technology called “enhanced visual inspection”.

## Objective 3:

- Review what the standards, literature, IFU, FDA warning letters, and other forms of information say on all types of visual inspection, especially borescope inspection.
- AORN Article 7/95
  - Residual Organic Debris on Processed Surgical Instruments
  - 32 Instruments checked
  - 90.6 % appeared clean
  - Microscopic examination revealed residual debris on 87.3% (27/32) instruments

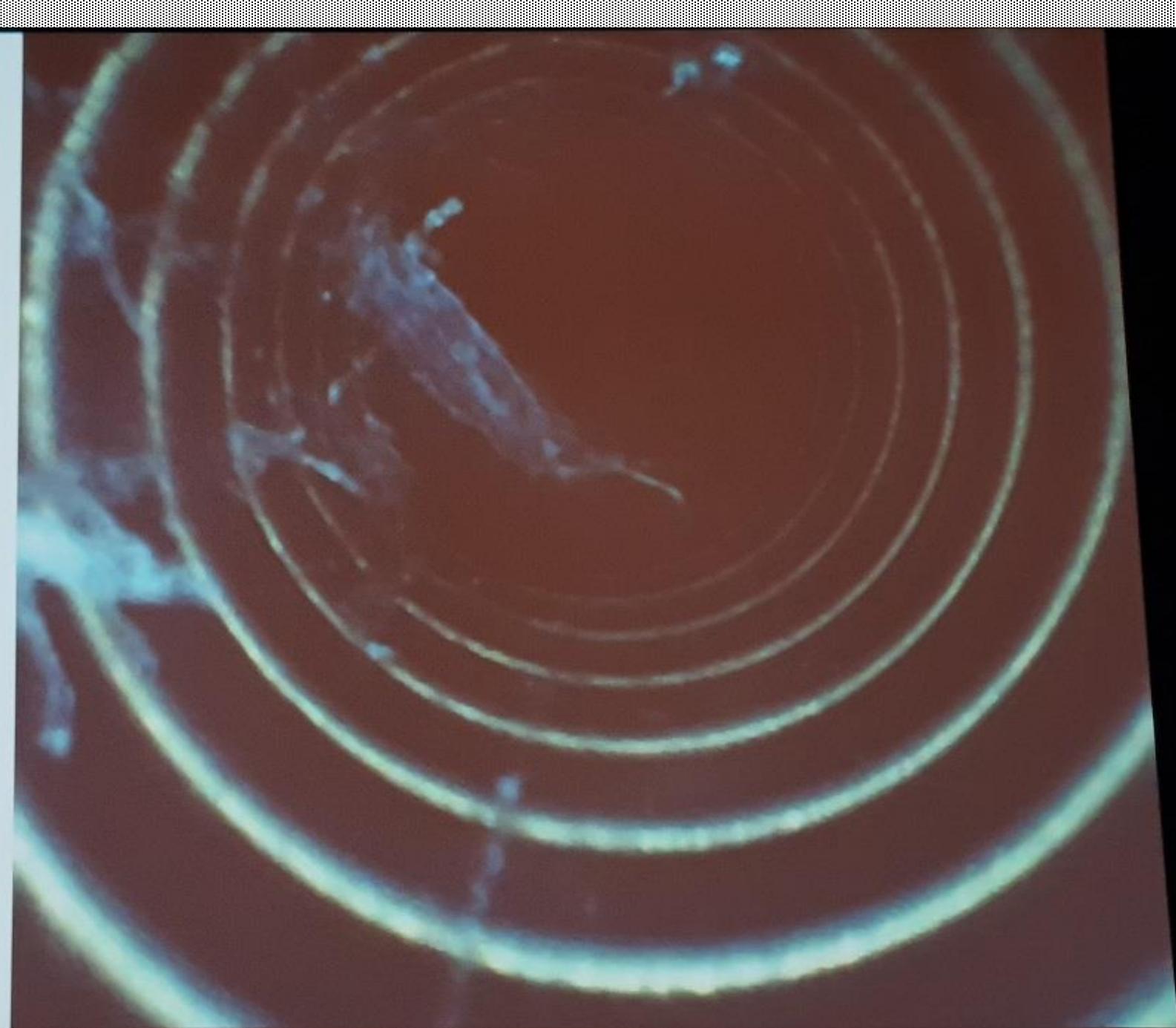


# U.S. FDA on Visual Inspection

## H. Visual Inspection

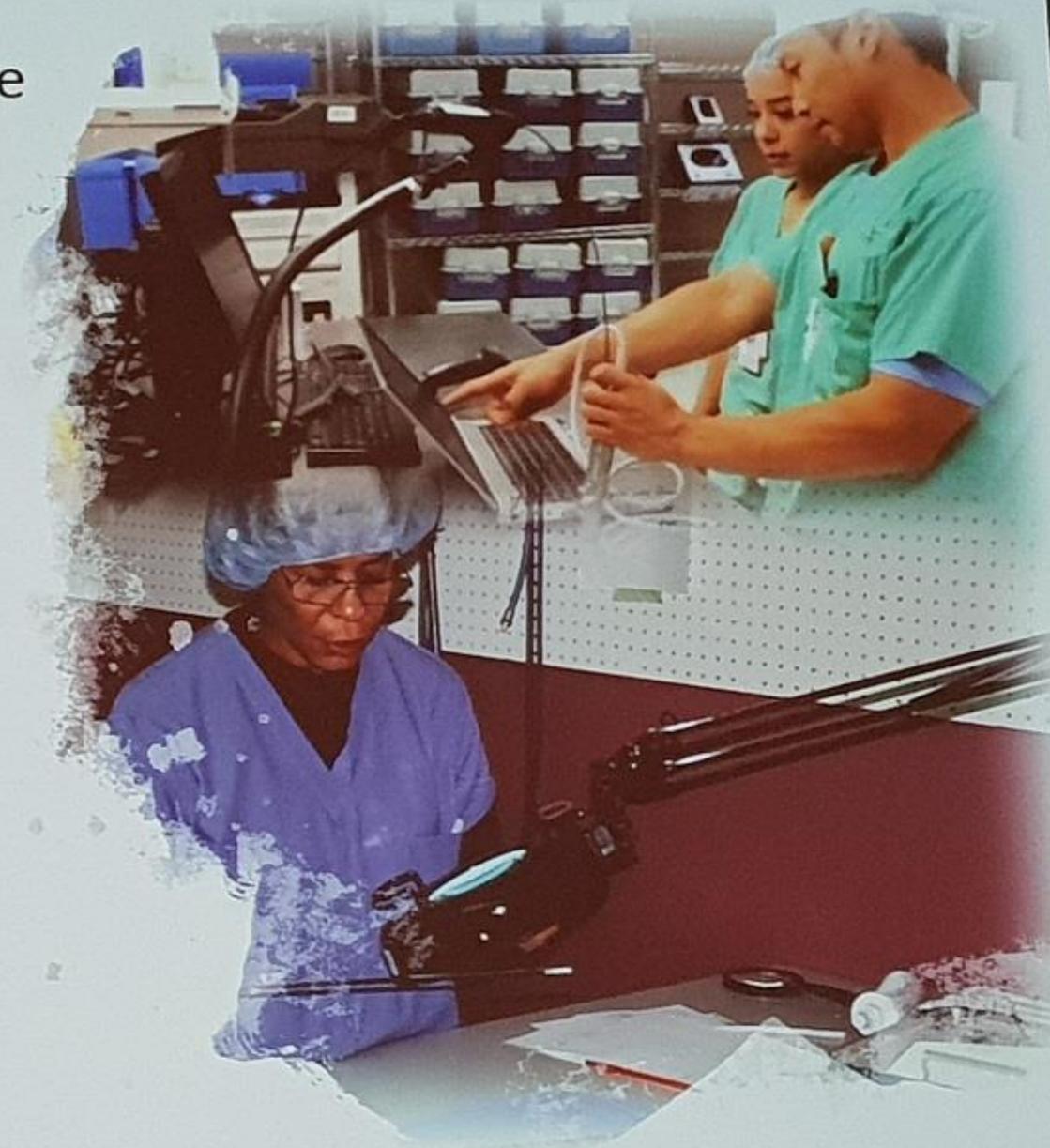
All routine cleaning instructions should include instructions for visual inspection, which may include use of magnification and adequate lighting. The instructions should advise the user that if the device is determined not to be visually clean at the end of the cleaning step, the user should either 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.\*

\* Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff Document issued on: March 17, 2015 Appendix E of this guidance was updated on June 9, 2017 ; page 17 ; section H



## Standards and Guidelines that Support the Practice of Enhanced Visual Inspection

- **The word(s) appear is some form in these documents**
  - *Inspect, inspection, visual, magnify, borescope, visually*
    - ESGNA – Position Statement for Endoscope Reprocessing
    - CSA Z314-18 on Device Reprocessing
    - HTM 01-01 on Decontamination of Devices
    - KRINKO: Hygiene Requirements for the Reprocessing of Medical Devices: 2012
    - ISO 17664 on Instructions for Processing Devices
    - ISO 15883 on Washer-Disinfectors
    - AAMI ST79 & ST91 – Best practice reprocessing for steam and HLD devices, respectively
    - US FDA Labeling for Device Reprocessing
    - AORN Guidelines for Device Reprocessing
    - SGNA Guidelines for Reprocessing Endoscopes
    - Manufacturer IFUs: In a review of over 900 plus IFU(s) the word(s) “inspect” or “inspection” appear



# Uphill Grime: Process Improvement in Surgical Instrument Cleaning

JAHAN AZIZI, BS, CBET, SUSAN G. ANDERSON, MSN, MBA, CPHRM, SHAWN MURPHY, ML, BSN, RN, SUSANNE PRYCE, JD

## ABSTRACT

After an investigation of cross-contamination from arthroscopic shavers, the US Food and Drug Administration issued an alert to hospitals about medical device reprocessing methods. In response to this, a team of risk management and instrument room personnel at a university hospital undertook a project that tested the manufacturer's recommended cleaning method for surgical instruments with the objective of determining the efficacy of automated instrument reprocessing and identifying a process that would produce a verifiably clean instrument after the cleaning process is performed. The quality improvement project focused on suction tips because they are used in most surgical procedures, are exposed to high levels of organic debris, and are difficult to clean. A variety of suction tips were cleaned and tested with a variety of processes and products to determine best instrument cleaning practices. Results of the project were eye-opening—debris was found where debris should not be, and the manufacturer's recommended cleaning method—the current practices—were not effective. *AORN J* 96 (August 2012) 152-162. © AORN, Inc. 2012. <http://dx.doi.org/10.1016/j.aorn.2012.03.018>

**Key words:** surgical instrument reprocessing, instrument sterilization, organic debris, perioperative safety, patient safety

Organic debris that remains in or on a surgical device is a threat to patient safety. In July of 2009, the US Food and Drug Administration (FDA) issued a Modification Devices Alert and Notice titled "Ongoing safety review of arthroscopic shavers."<sup>1</sup> The objective was to bring awareness to the possibility that tissue fragments or other debris can become lodged inside the lumens of surgical instruments, specifically arthroscopic shavers. The FDA recommended that health care personnel review their

facility's instrument reprocessing procedures, both to ensure compliance with the operational guidelines of the manufacturers and to determine whether the recommended cleaning process actually yields the results necessary to ensure adequate sterilization, because what is not clean cannot be sterilized. Organic debris is persistent, and its elimination requires dedication of resources and collaboration among device manufacturers, medical professionals who use the instruments, instrument-specific cleaning process

<http://dx.doi.org/10.1016/j.aorn.2012.03.018>  
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INSIDE THE CURRENT ISSUE

People & Opinions



**Are you meeting the current manufacturers' requirements?**

Construction for Use (CFU) is an exciting development of your business surgical instruments.

By John A. Smith, MD, PhD

A quick Google search for "surgical instrument" yields hundreds of thousands of hits. It has been two years since the issuing of alerts by the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Association for the Advancement of Medical Instrumentation (AAMI), and many other organizations to the challenges related to cleaning the internal channels of medical devices. Despite this, however, most hospitals are still unable to verify the cleaning of surgical instruments with lumens.

A new alert—July 7, 2010, FDA sent a safety alert to health care institutions stating that:

- FDA has become aware of instances in which pieces of tissue have remained within certain arthroscopic shavers, a device used in some arthroscopic surgical procedures, even after the cleaning process was followed. In some cases, the cleaning process was not followed according to the manufacturer's instructions. Reports submitted to FDA suggested that the tissue retained was not evident to the naked eye... because retained tissue in these devices can compromise the entire sterilization process.
- Consider inspecting the inside of the device following cleaning to ensure that any tissue that has been cleaned or pulled. There may be multiple situations in our attention area a 30mm video scope to inspect the channels of the shaver head piece.<sup>1</sup>

We know that the FDA's safety alert was initiated based on a CDC investigation into cross-contamination at hospitals. The CDC found two probable sources—debris inside a head field at Percutaneous Closure, used to close wounds and incise during arthroscopic surgery; and inside a long, metal tube called an inflow/outflow cannula, used both to irrigate and suction the surgical site. During the investigation, surgical tools were inspected with a tiny video camera revealing human tissue and bone stuck in both devices. The camera also found a bone fragment in a cleaning brush.

Click the link at these surgical instruments which have been cleaned using the manufacturer's recommended procedure and make an observation that you are not of them.

By Tom, MD, Manager, Head of OR, University of Michigan, Ann Arbor, MI

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May 2015

Worth Repeating

Surgical waste creates a serious environmental hazard resulting in increased greenhouse emissions. Littered waste, not to mention the serious problems of recycling waste and products to landfill, contribute to the waste problem. A waste-to-energy plant could help reduce the waste problem.

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These articles will have their respective authors' names and titles listed at the end of each article. If you are interested in contributing to the journal, please contact the editor at [editor@www.aorn.org](mailto:editor@www.aorn.org).

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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<sup>1</sup>, John E. Eiland, RN, MS<sup>1</sup>, Miriam R. Amelang, BA<sup>1</sup>, Otis L. Heymann, BA<sup>1</sup>, Sarah B. Held, RN, MBA<sup>2</sup>, Michael J. Shaw, MD<sup>3</sup>

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

#### Introduction

- Contaminated endoscopes have caused outbreaks of multidrug-resistant organisms<sup>1</sup>
- During one outbreak investigation, investigators dismantled an endoscope and identified<sup>2</sup>
  - Brown staining, scale, and a small crack in the distal tip
  - Phenoxymethyl penicillin identical to outbreak strain
- In another outbreak investigation<sup>3</sup>
  - 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)<sup>4</sup>

<sup>4</sup>Results of routine reprocessing and follow-up assessments pending

#### 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<sup>5</sup>
  - 29% harbored viable bacteria

<sup>5</sup>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



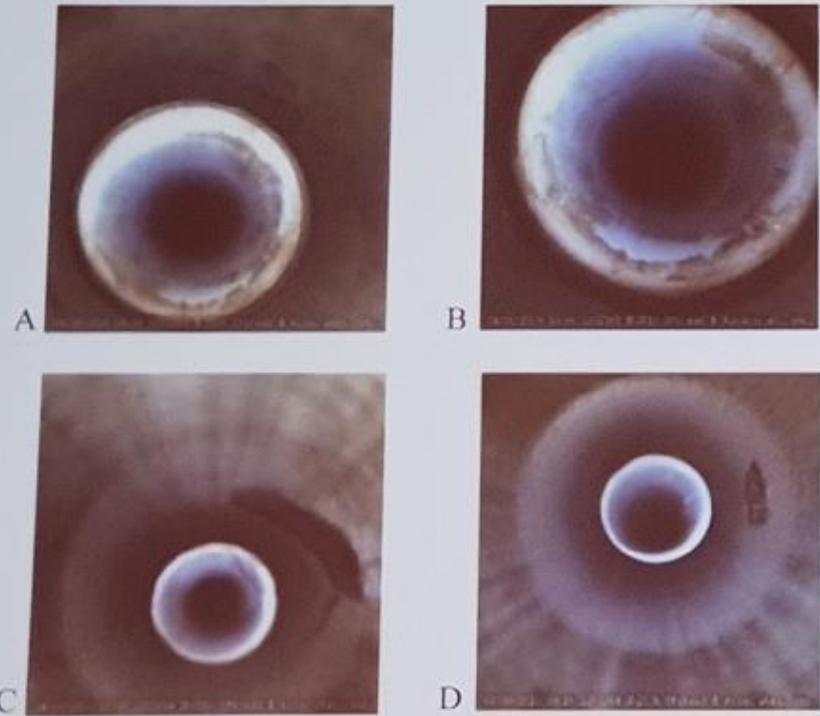
Photo 4. Scratches, non-intact lining, and brown staining in the biopsy section of a colonoscope



Figure 1. ATP test results after manual cleaning

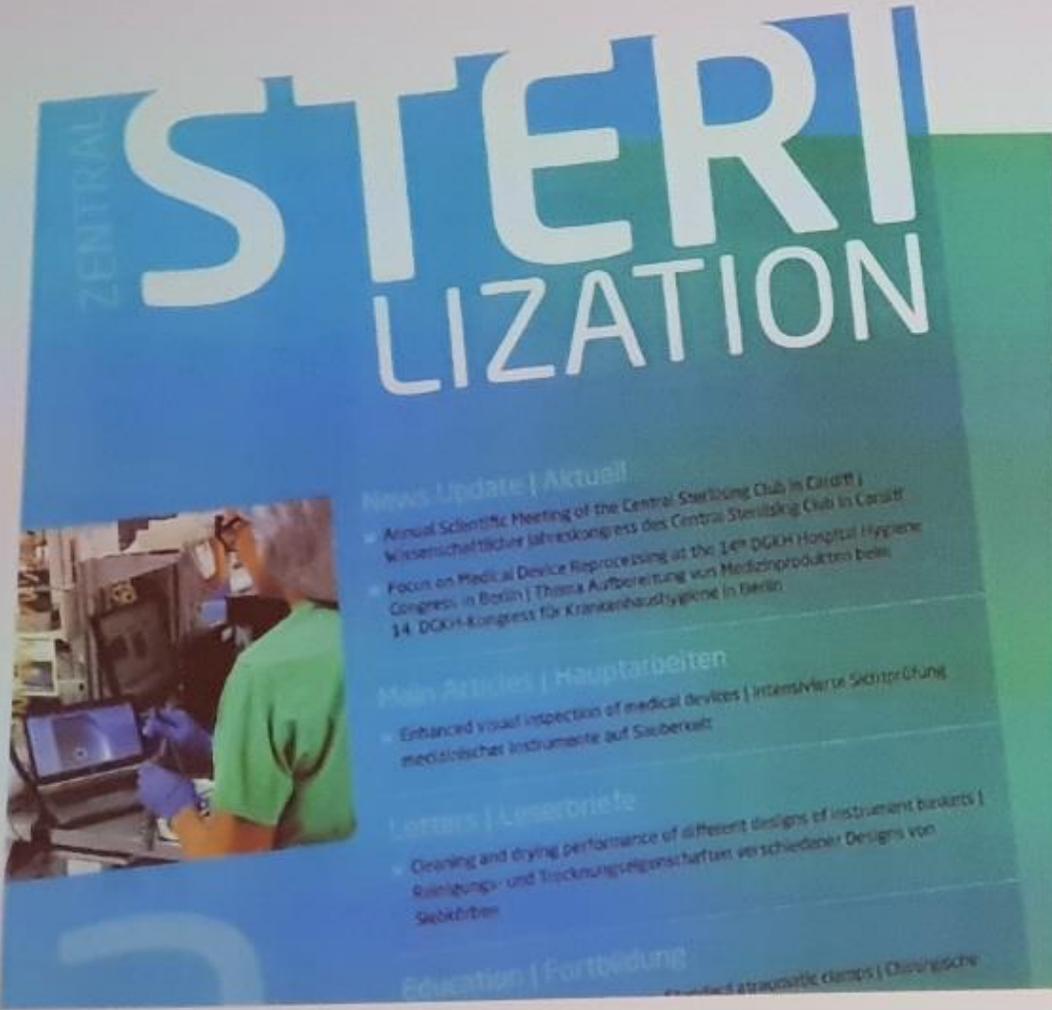


# Support for using enhanced visual inspection



**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 sent for repair, manufacturer determined there were critical defects



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- Enhanced visual inspection of medical devices | Intensivierte Sichtprüfung medizinischer Instrumente auf Sauberkeit

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From the Field

# Enhanced Visual Inspection of Medical Devices

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**Conflict of interest:**

All authors confirm that there is no conflict of interest according to the guidelines of the International Committee of Medical

**Abstract**

**Background:** Recent incidents of infections received from contaminated arthroscopic shavers and flexible endoscopes have led to changes in how sterile processing professionals visually inspect these medical devices. Certain shaver manufacturers have updated their Instructions for Use (IFU) to require the use of additional tools to inspect their medical devices.

**Materials and methods:** This three-phase study explores the development and implementation of new technologies in the area of enhanced visual inspection of medical devices. Phase

assembly, but as a critical part of ensuring that they were assembling a visually clean instrument.

**Conclusion:** Our borescope data for arthroscopic shavers showing that 32% of cleaned devices were actually inadequately cleaned supports the need for better integration of borescope examination into facilities that reprocess such devices. These advanced visual inspection tools are cutting edge technology that progressive sterile processing departments are utilizing to deliver safe and ready to use medical devices to the next patient.

Published articles supporting the importance of enhanced visual inspection of medical devices

# 2018\*

“...Over the course of **97 inspections** in 59 patient ready endoscopes (38 duodenoscopes/echoendoscopes), **the most common findings were scratches (86%), channel shredding (59%),** and intrachannel debris (23%). Among endoscopes dried by the use of forced air and overnight vertical storage, none had evidence of retained moisture, whereas 28% had moisture after storage alone without dedicated drying after HLD.... At the **final assessment,** borescope examination of **20 patient-ready endoscopes** after drying and overnight vertical storage revealed various findings, including discoloration, scratches, and filaments of debris involving the channel. On the basis of some of these discoveries and of the microbial and biochemical findings, **85% (17/20) endoscopes were sent for repair, and the majority were found to have at least 1 critical defect reported by the manufacturer....”\***

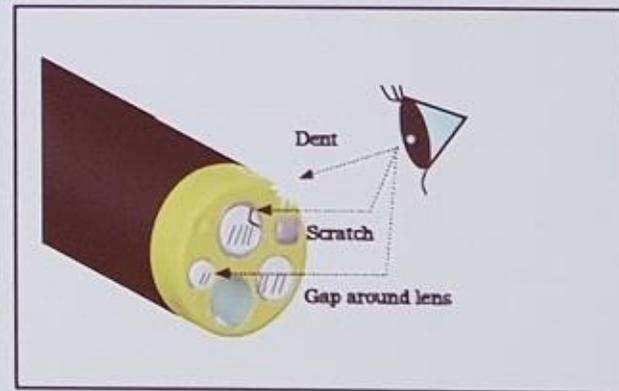
\* EDITORIAL ; Volume 88, No. 4 : 2018 GASTROINTESTINAL ENDOSCOPY

# IFU on the Distal Tip \*

**WARNING:** Endoscope users must inspect the equipment according to the following procedure before use. If any abnormality is observed, stop using the equipment and send it to Olympus for repair. Using a damaged endoscope may cause the lens to detach from the endoscope, and poses a risk to patient safety.

1. Wipe the surface of the lenses with a lint-free cloth.
2. Inspect the distal end of the endoscope, specifically the objective and light guide lenses, to determine if there are any chips or scratches on the lenses, or any missing adhesive or gaps in the adhesive surrounding the lenses. Do not use an endoscope with missing or deteriorated adhesive.
3. Check that the endoscopic image is not foggy.

**WARNING:** If the endoscopic image appears foggy during a patient examination, immediately withdraw the endoscope from the patient. Using an endoscope with a foggy image may cause patient injury.



## FDA – Safety Alert

### How are you going to meet these requirements?

1/17/2017 - Posted

ED-3490TK Video

Duodenoscope by Pentax:

FDA Safety

Communication - UPDATE -

Follow Pentax Validated

Reprocessing Instructions

“...Immediately remove from service for assessment, and repair or replace any duodenoscope that shows visible signs of damage. Examples of damage may include: loose parts, damaged channel walls, kinks or bends in tubing, holes in the distal end, cracks and gaps in the adhesive that seals the device’s distal cap or other signs of wear or damage...”

# IFU Support for using a Flexible Inspection Scope

- Arthrex - Adapteur Power System™ II (APS II) Shaver Hand pieces -DFU-0154r10\*
- INSPECTION AND MAINTENANCE
  - Step 4 in the DFU (IFU)
    - “...Check device for visible soil. It is recommended that the cannulation be inspected with an illuminated, magnifying scope. Clean the device using the guidelines for manual cleaning if any soil is visible...”

\*[www.arthrex.com](http://www.arthrex.com)

- STRYKER Shaver HandPiece - 1000400638 R-2012/10 \*

- INSPECTION – EN 21
- Step 9
  - “...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...”

\* [www.stryker.com](http://www.stryker.com)



## Objective 4:

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- Show with pictures why enhanced visual inspection with a flexible inspection scope (borescope) is needed in today's medical device reprocessing departments.
  - Shavers
  - Endoscopes
  - Suctions



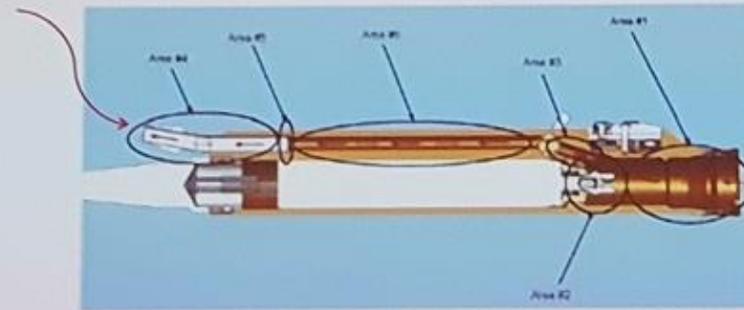
Before you go down that rabbit hole on Enhanced Visual Inspection, ask yourself this...

- What medical devices am I going to look at?
- What am I looking for?
- What will I do if I see something?
- Where in that medical device should I be inspecting (looking)?
- What are the best tools for enhanced visual inspection?
- Do I have a policy in place for this new technology?
- Who has the most knowledge in this area?
- Let us look at these devices
  - Shaver
  - Endoscopes
  - suction

# Recent results from inspections of shavers in various facilities

Inspect inside the lumen step area

inspect inside the drive fork area



# Just the Facts

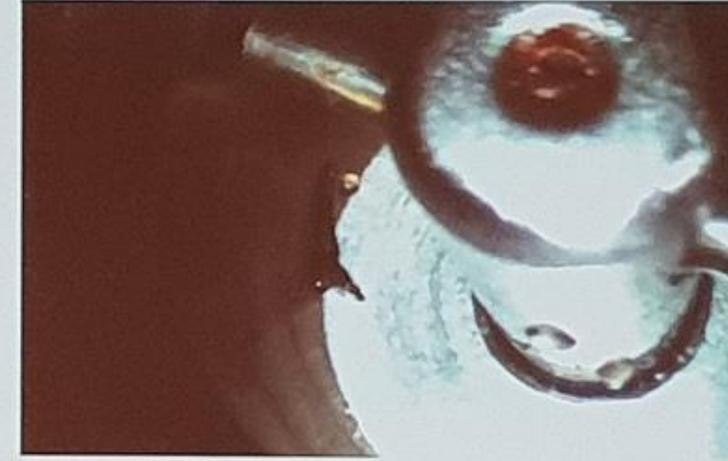
- Three departments felt their shavers were clean, sterilized and ready to go
  - 4 out of 7 shavers that were presumed clean were dirty
  - 1 out of 2 shavers were dirty
  - 3 out 3 shavers were dirty
- All departments felt they were following the IFU
- None had any type of flexible inspection scope



# Videos of Dirty shavers taken with a flexible inspection scopes



# Examples of debris found in shavers:





**Medtronic**

## Reprocessing Instructions

### Microdebriders

StraightShot M5, StraightShot M4, StraightShot Magnum II, StraightShot III or  
Midas Rex Spine Shaver

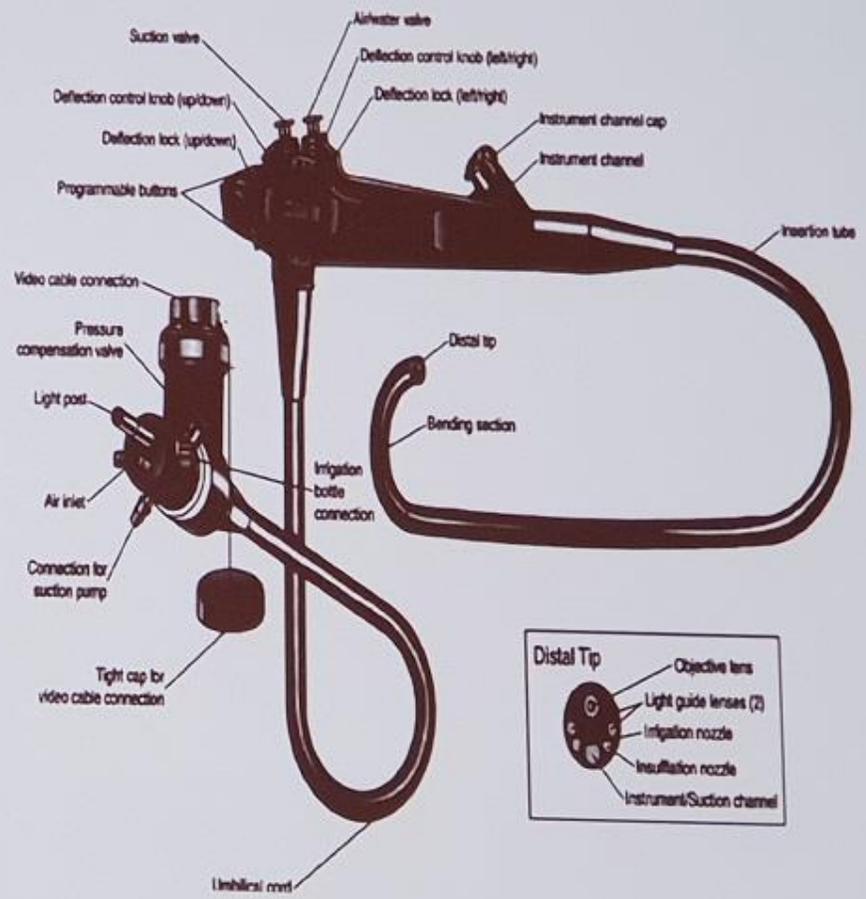
Reprocessing Instructions  
Cleaning and Sterilization instructions are  
subject to change. Up to date instructions  
are available online at [manuals.  
medtronic.com](http://manuals.medtronic.com).  
68E3282 F

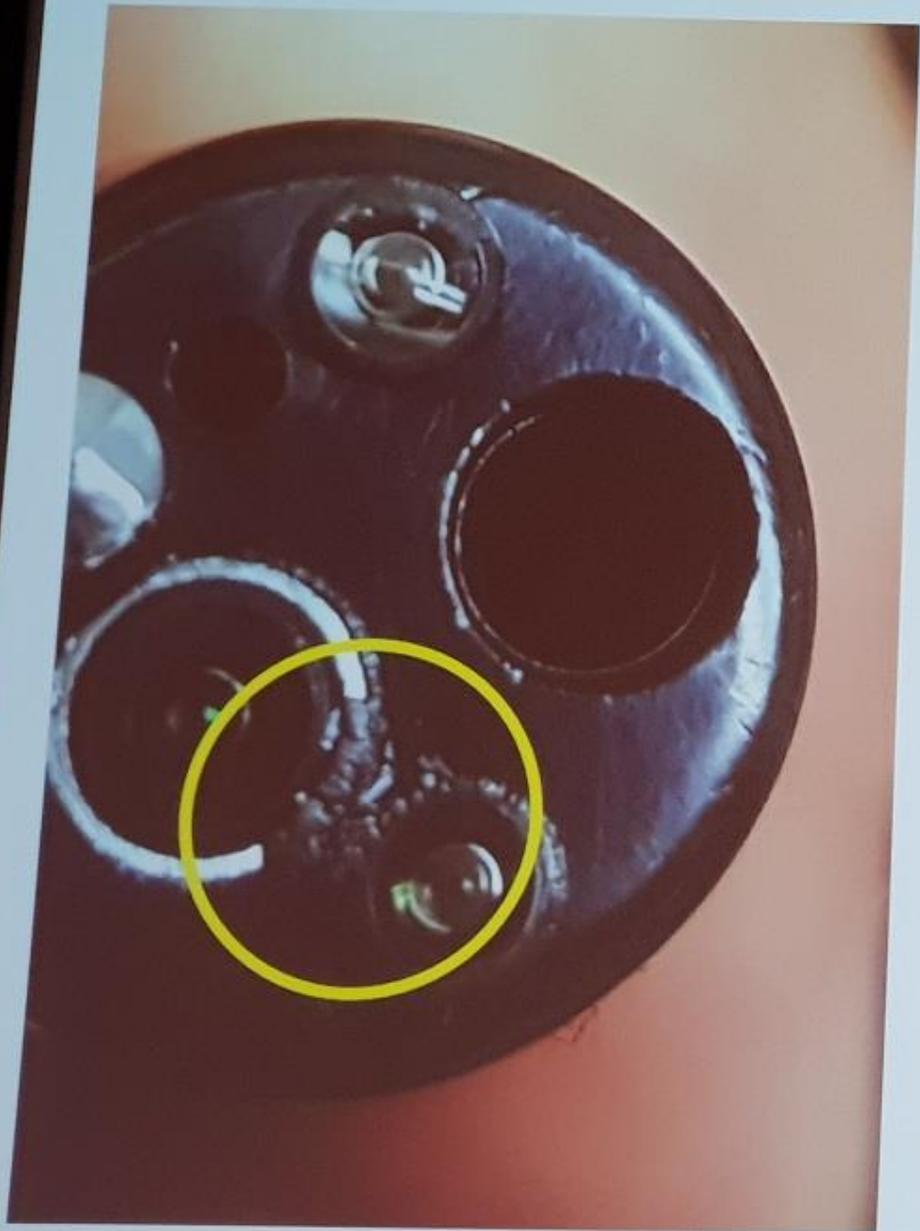
- They make one simple statement:
  - “Visually examine for cleanliness”.
- Ask yourself this; is this not a type of a shaver?
  - Do you think it would have the same issues as an orthopedic shaver?
  - Should you examine this with some type of enhanced visual inspection tool?
    - Remember the rabbit hole
    - What will you do if it is dirty



# Where to inspect a scope externally

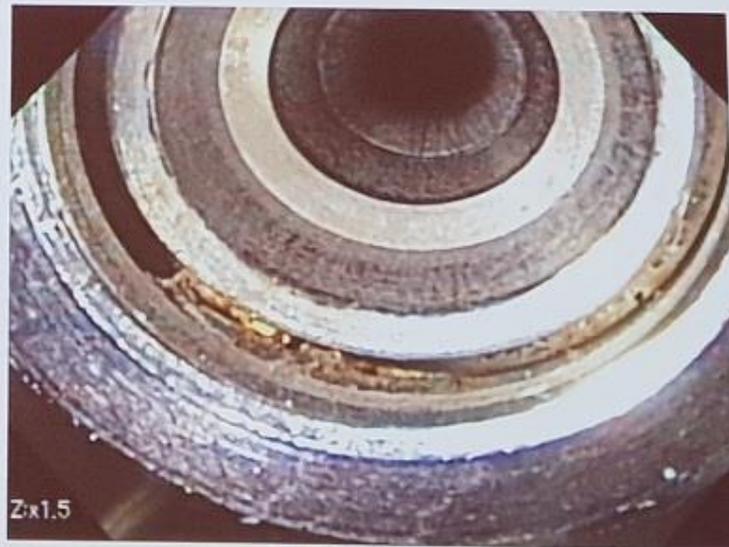
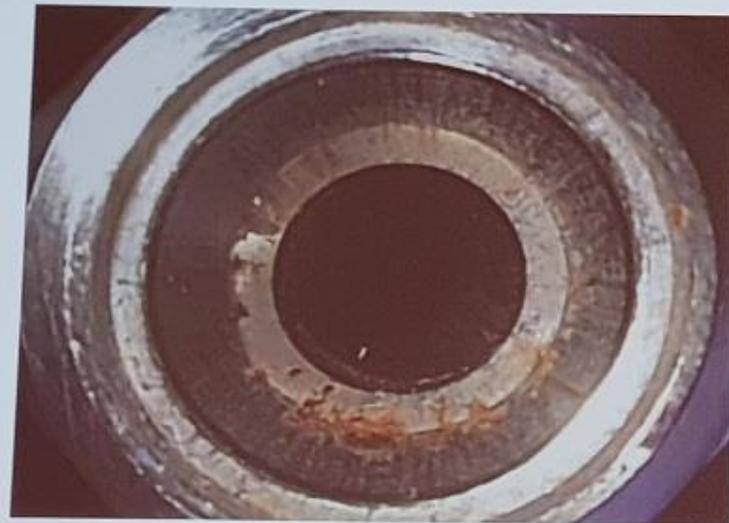
- Instrument/suction channel
- Valve openings
- Biopsy
- Distal tip
- Elevator
- Connection points within scope
- Forceps elevator
- Accessories





Inspection at the distal tip,  
front and sides

# Examples of Debris and Damage Found in Endoscopes:





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.

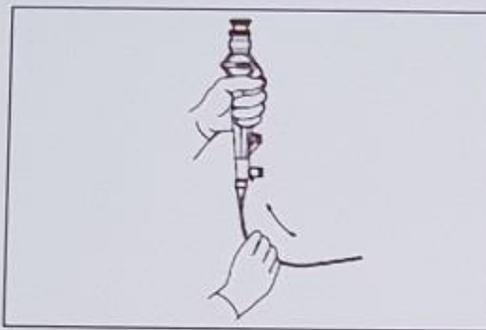


Figure 3.2

5. Visually inspect the covering of the bending section for sagging, swelling, cuts, holes or other irregularities.
6. Gently hold the midpoint of the bending section and a point 10 cm from the distal end of the endoscope's insertion tube for scratching, cracks, stains or other irregularities.



OES CYSTONEPHROFIBERSCOPE CYF-5/CYF-5A

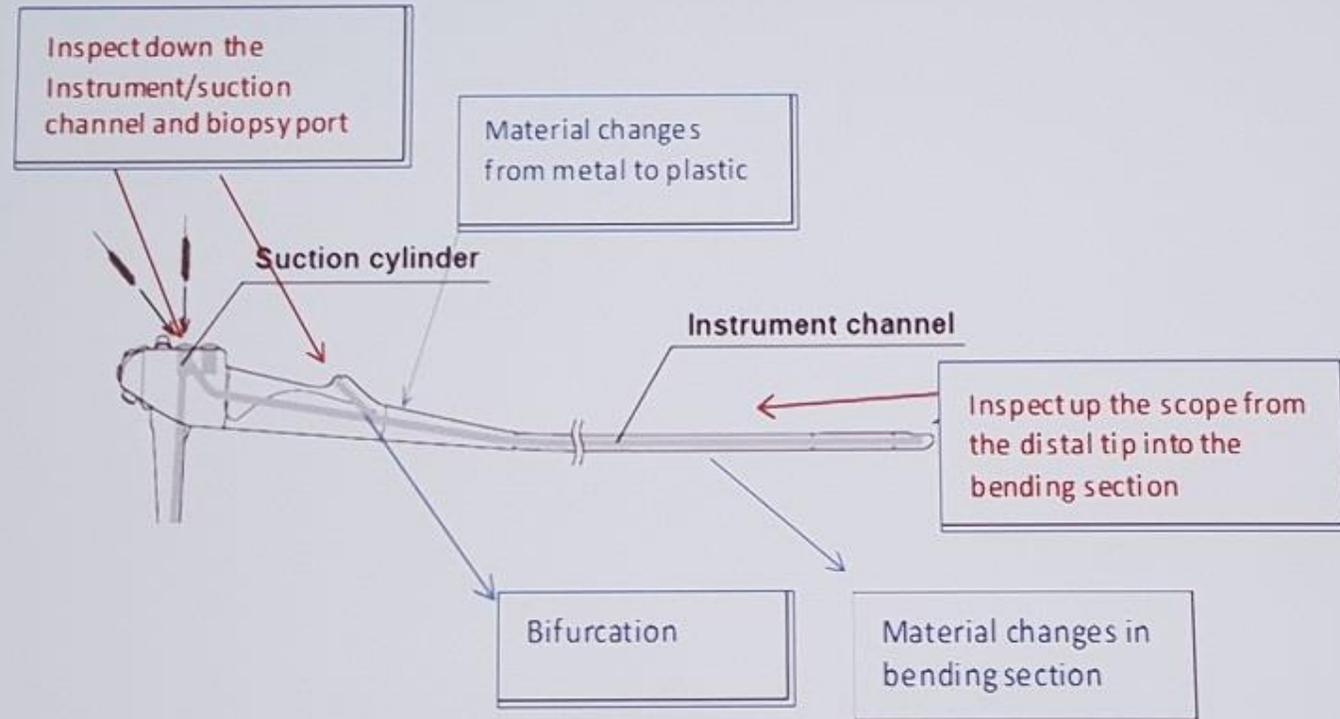
Early  
inspection  
of an  
Endoscope

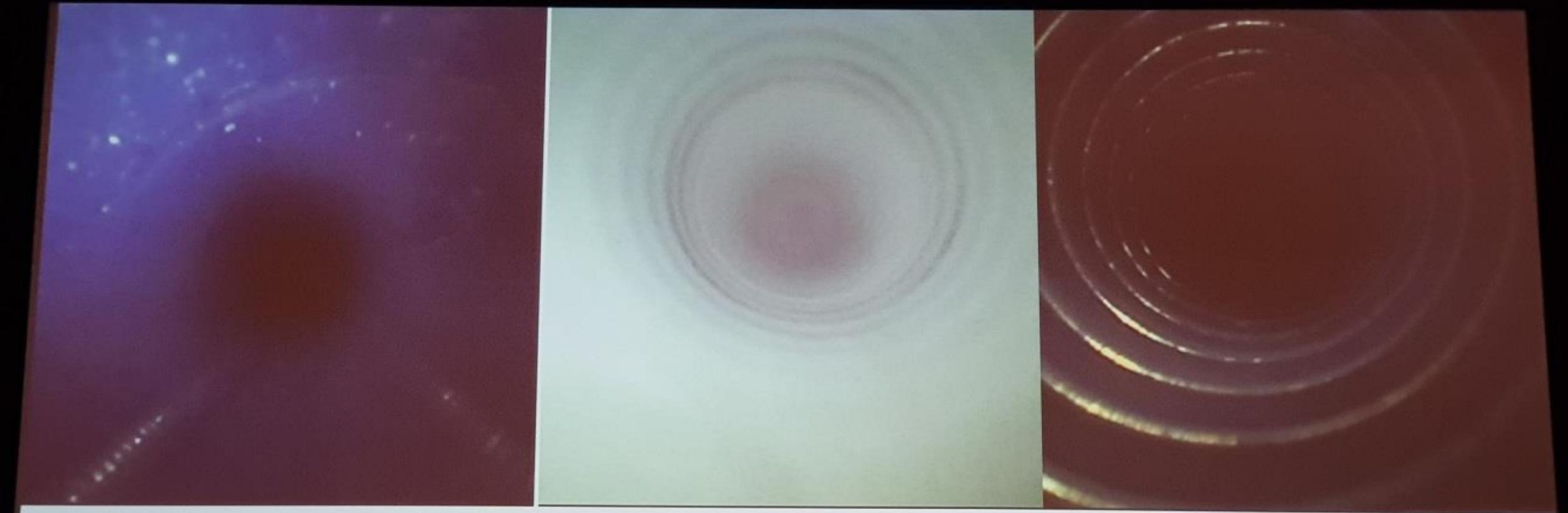


70

117

# Where to inspect inside a scope





## Clear Channels

This what it is supposed to look like!



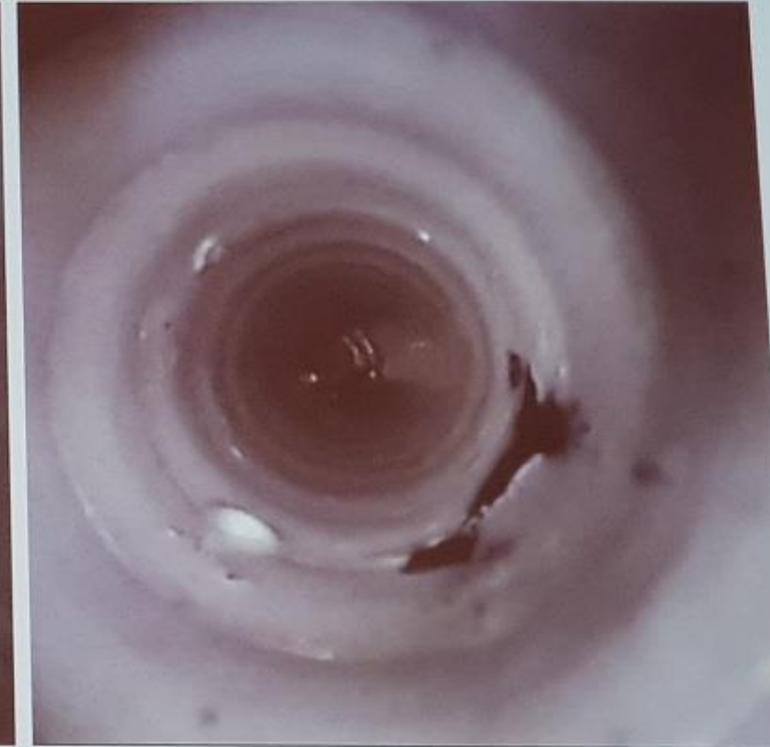
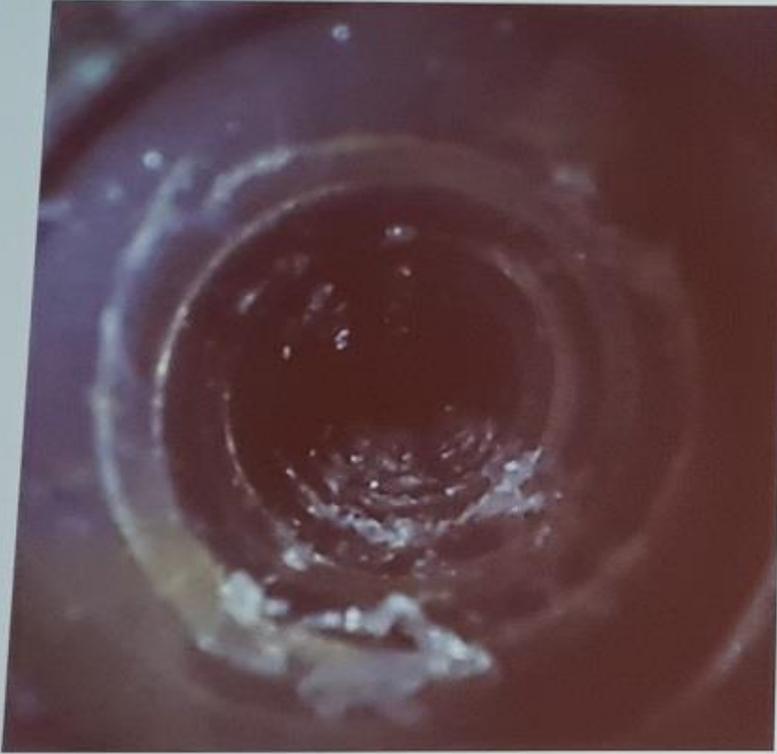
Fluid and Simethicone residual identified in a scope after processing in 19 of 20 scopes inspected



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

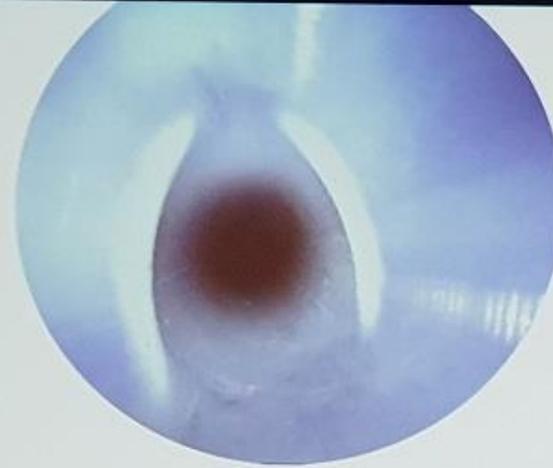
## Examples of Borescope inspection Fluid

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Examples of Borescope inspection  
Staining, Moisture

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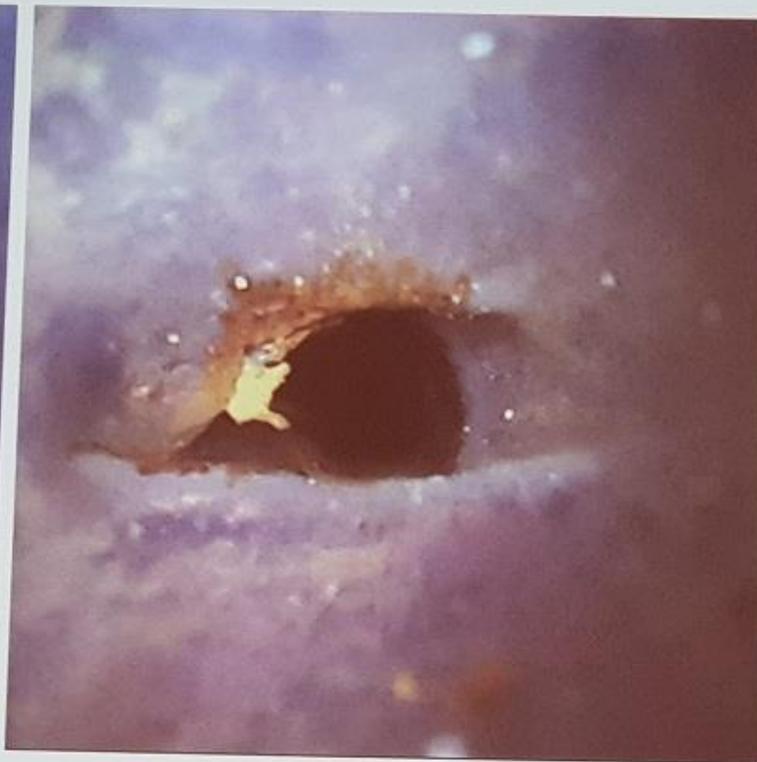


Examples of Borescope inspection  
Pinching, dents, crush marks of the  
inner channel.

If you see these types of restrictions  
in the biopsy channel, you should  
send out for repair.

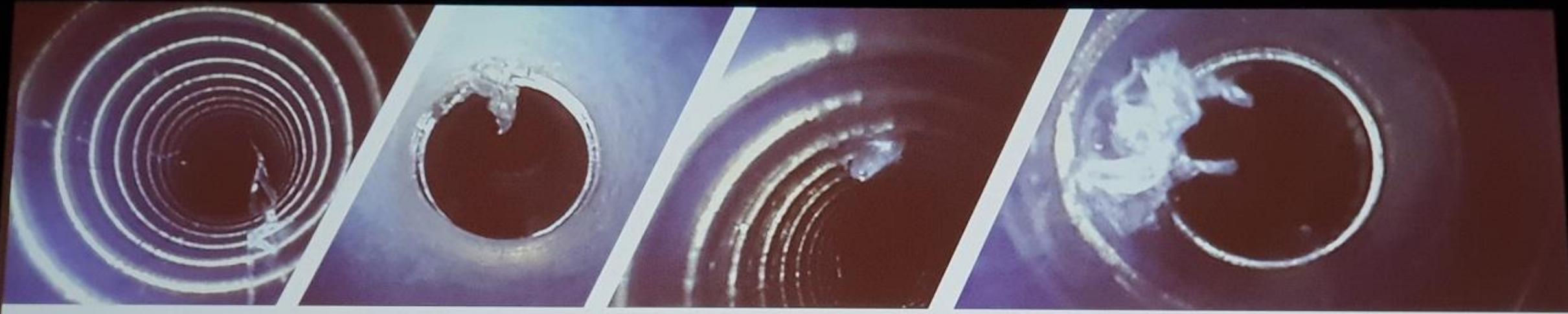
A brush can pass through the  
opening and you would never know  
you had an issue.





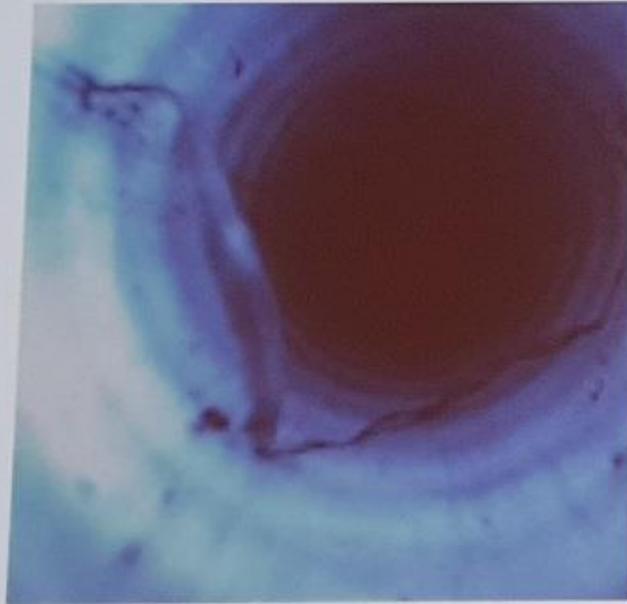
Examples of Borescope Inspection  
Staining and Debris

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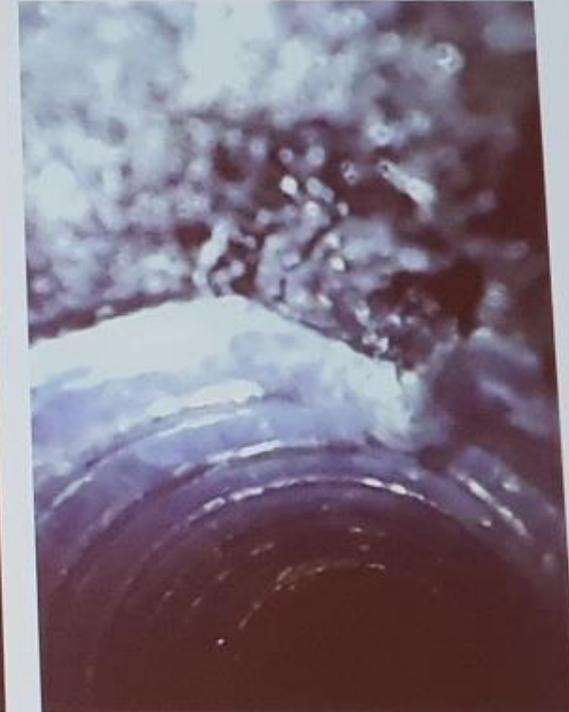
Examples of  
borescope inspection:  
“Stalactite” of Teflon

## Inside the Lumen of an Endoscope



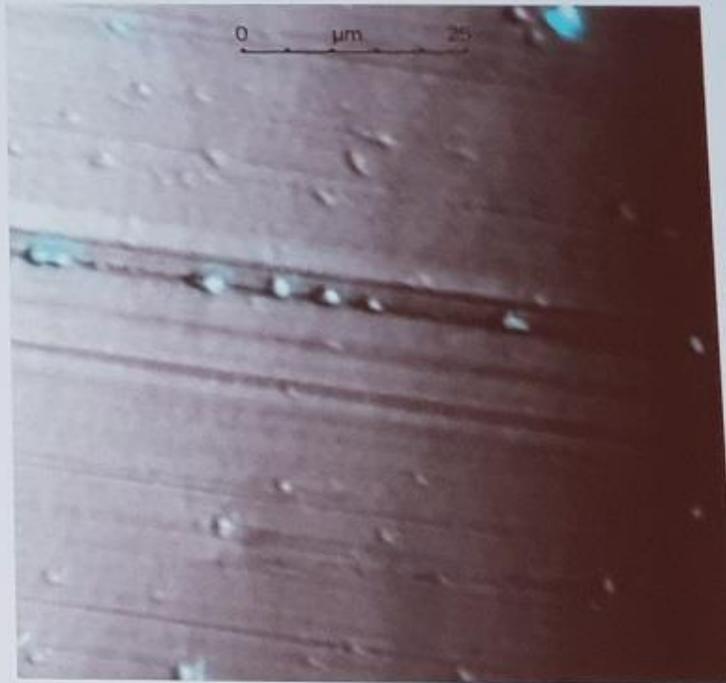
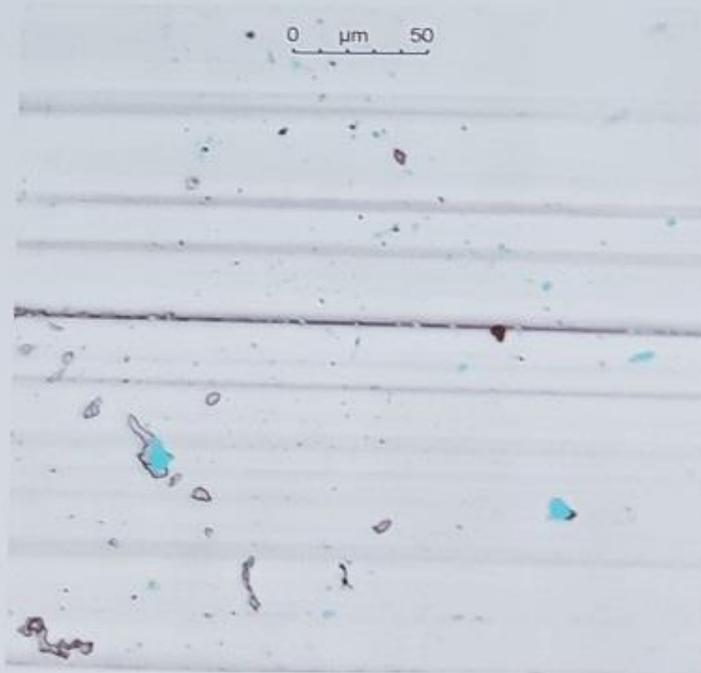
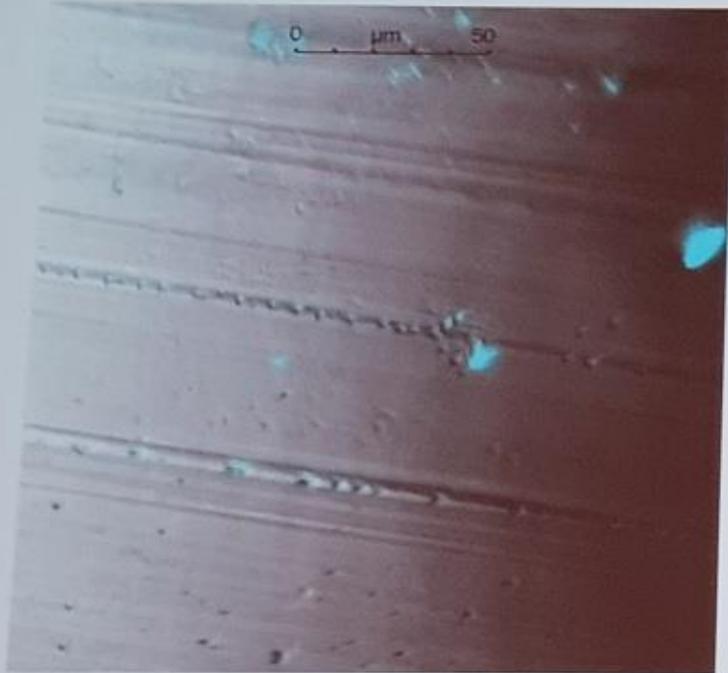
Actual scraping/peeling of the inner lumen of an endoscope found during inspection, after the cleaning process.

This needs to be sent back for repair. This could dislodge and go into a patient during examination.



Examples of Borescope inspection  
"Ice Dam"

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Bacteria Groovin' in the Gouges  
Microscopy Images  
(source: US FDA OSEL)

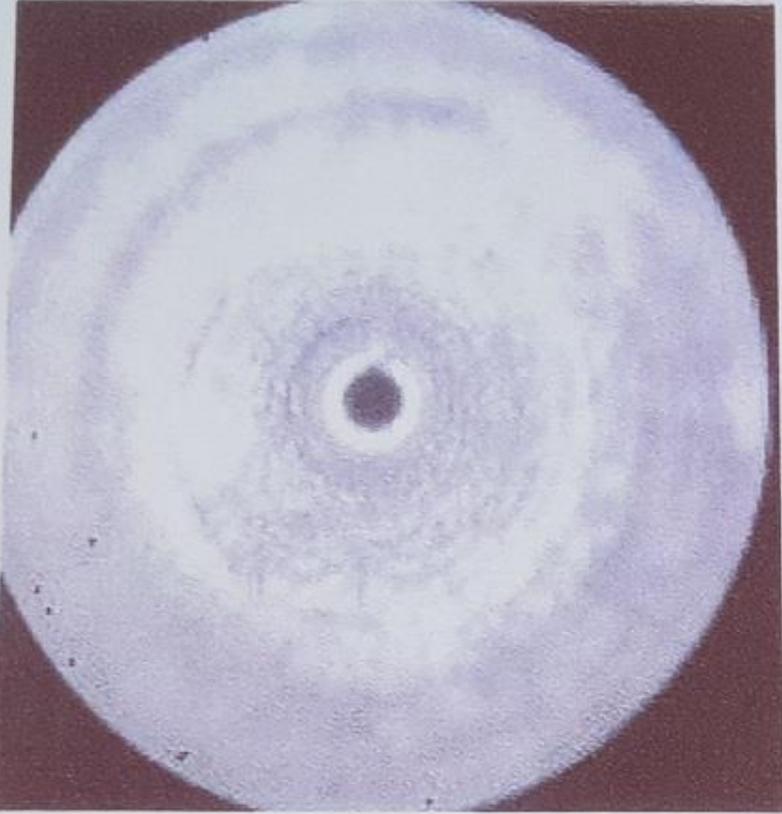
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# Suctions

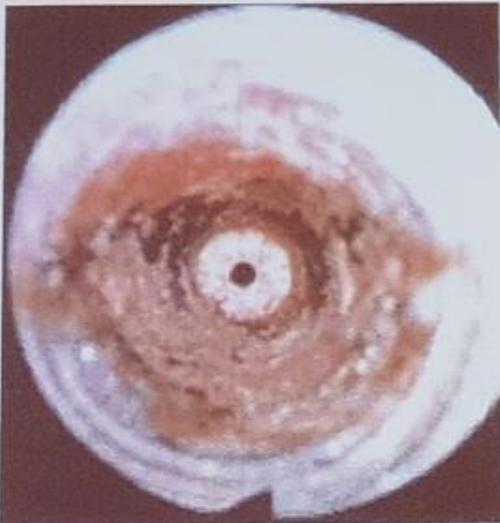
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- Rabbit hole question
- If the standard is visually clean and you start inspecting suctions
- How many times will you re-clean a suction before you stop using it
- Suctions: many types, many sizes...
- Ask your self this question: What if I started to look at all my suctions? What would I find and what would I do?
- Close my CSSD
- Let us look at some suctions

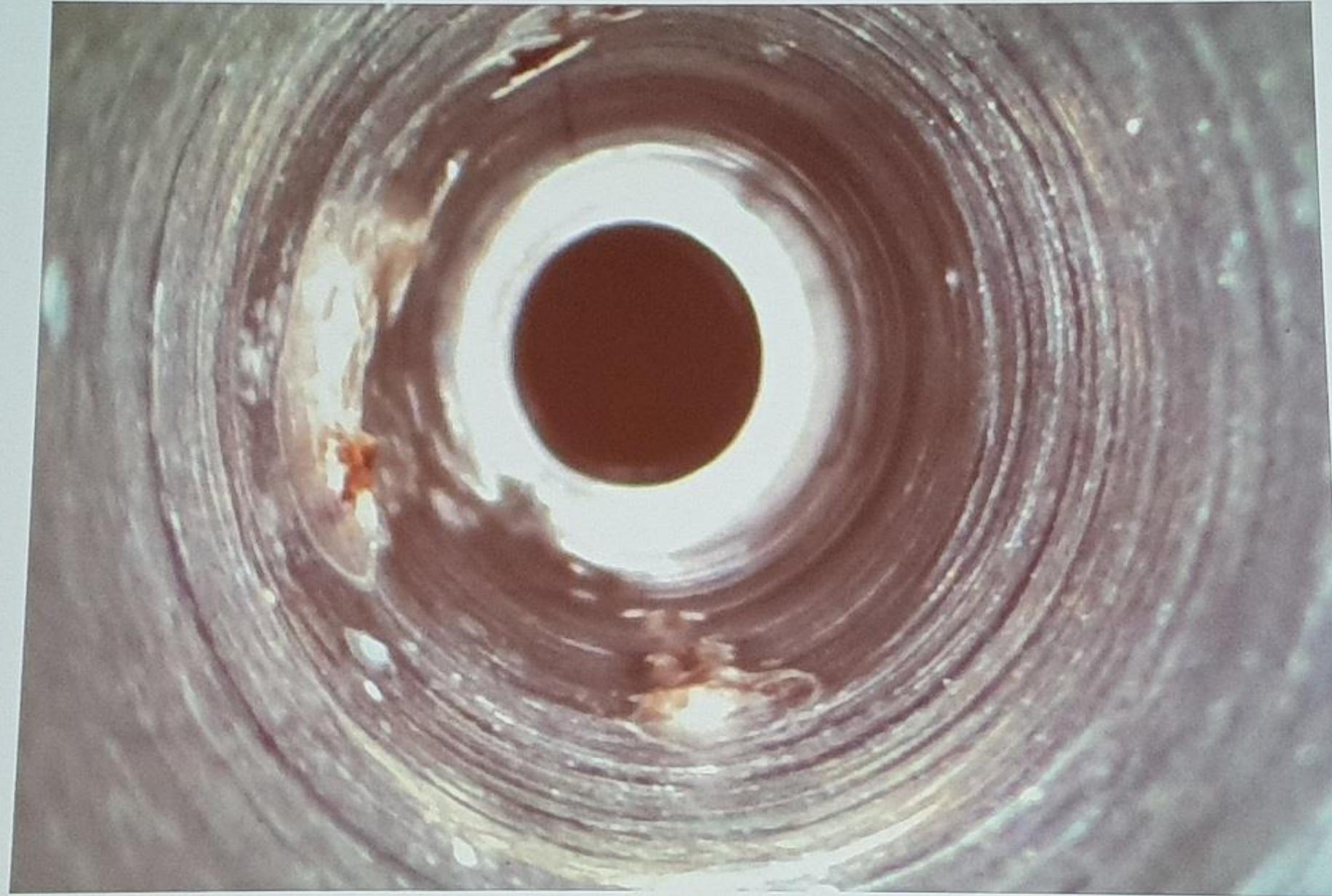




A new Suction: Notice how we do not see any red or dark colors. Inspected new, right out of the package.



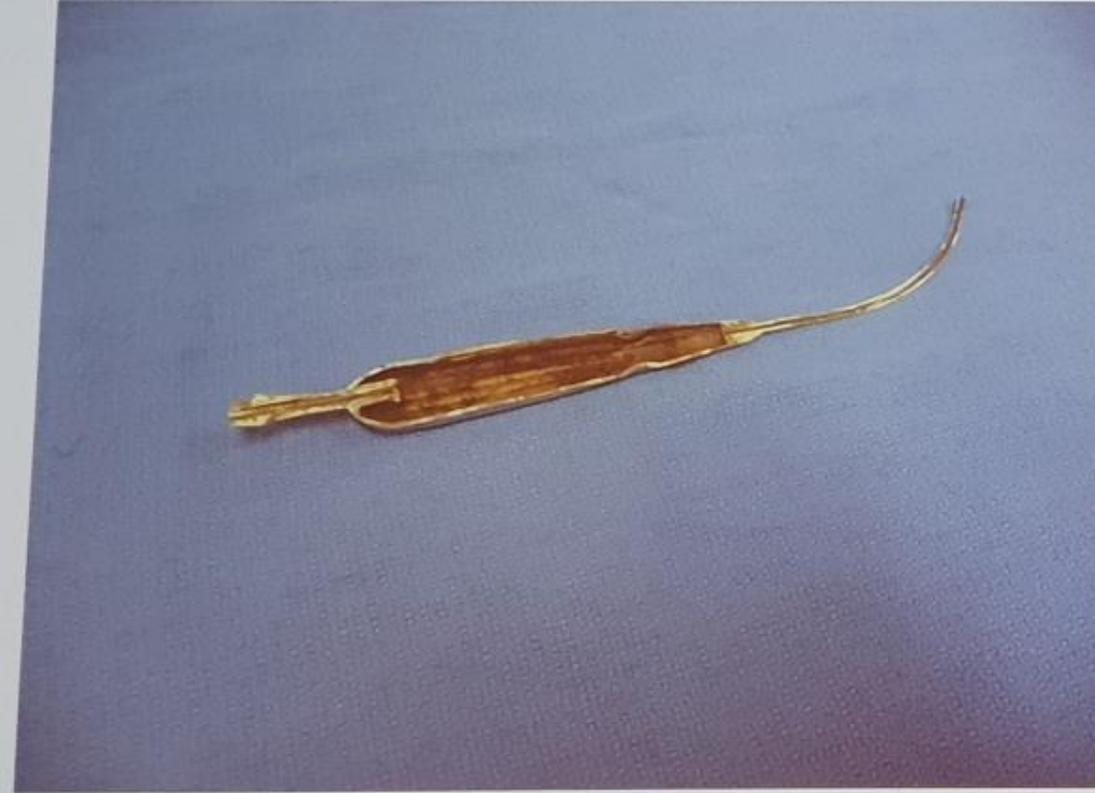
These are pictures of used suctions. Notice the red and brown. This should not be inside the suction. This is organic soil and other bioburden not removed after cleaning. We do not know how long they have been used. But what we do know is that they are visually dirty.





# Inside A Suction

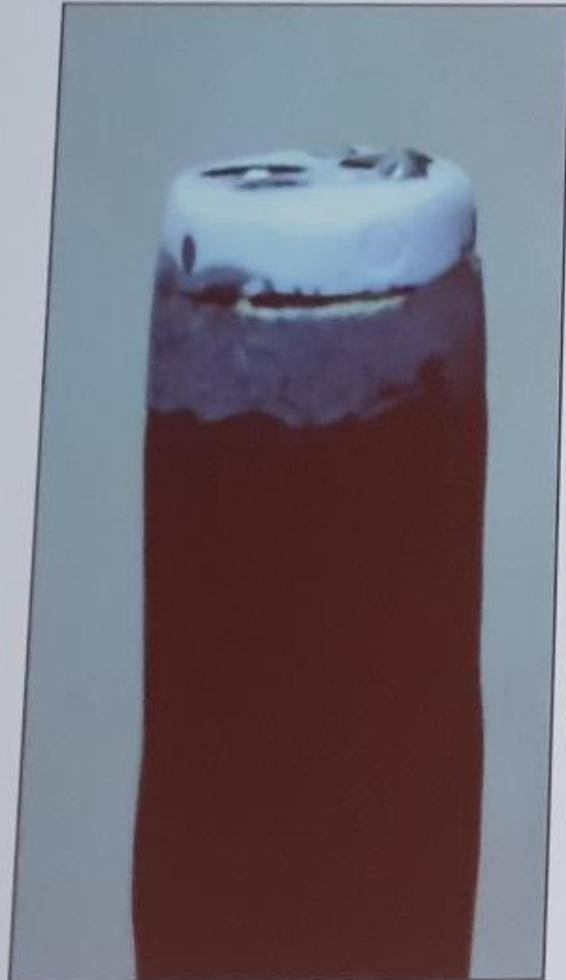
Pictures supplied by:  
Jahan Azizi of the  
University of Michigan



Easy solution for this: Replace with  
disposable, single use.



## Now what?

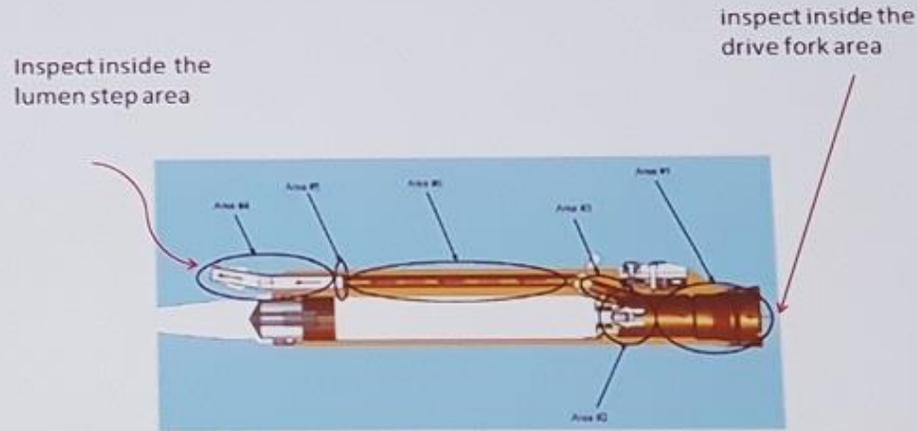


- I have just reviewed the case for having a variety of enhanced visual inspection tools in your CSSD.
- Build quality into instrument reprocessing by incorporating enhanced visual inspection of flexible endoscopes and difficult to clean medical devices.
- Evaluate products available to ensure best utilization in all inspection scenarios. “Right Inspection Tools” at all locations.
- Ability to save and record pictures
- Ability to have a preview screen
- Determine guidelines for all facilities on what devices will be inspected, the frequency of inspection and how to evaluate/interpret devices seen as not clean or damaged.
- Provide education and training to all technicians on how to best utilize these new tools following corporate policy.
- Develop a standardized policy and implementation plan for the corporation.

# Define best practices for enhanced visual inspection of medical devices

- The facility decides what to look at
  - Shaver (must)
  - Other medical devices
- Committee
- Quality Improvement Program
  - IQ
  - OQ
  - PQ
- Create a sample policy
- Flow chart
- Start a picture file
  - Each device
  - New, never used pictures
  - Critical point for examination
- Train staff what to look for
- Partner with the expert vendor in the field

- The critical parts of the shaver to visually inspect



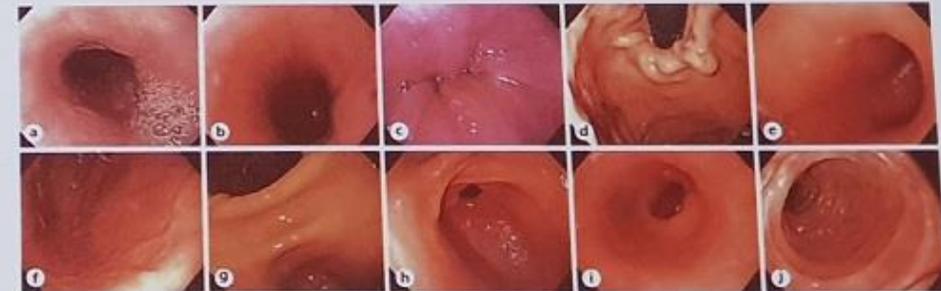
# Our Path has been paved

- **Learn from our customer**
  - Endoscopist
    - They support training using video and images
- **Image Documentation in Gastrointestinal Endoscopy: Review of Recommendations**
  - This outlines the importance of using images for training and quality control to be a better endoscopist
  - “For both photo and video documentation, the best quality imaging requires a clear lens, optimized focus and light, sufficient luminal distension, and optimal cleansing of the area of interest”.
  - “Accurate and adequate image documentation is an essential part of GI endoscopic reporting. At the present time, systematic photo documentation is recommended by major endoscopic societies, including the ESGE and ASGE, and has become an integral aspect of quality control”.

## Image Documentation in Gastrointestinal Endoscopy: Review of Recommendations

Susana Marques<sup>a</sup> Miguel Bispo<sup>a</sup> Pedro Pimentel-Nunes<sup>b</sup> Cristina Chagas<sup>a</sup>  
Mário Dinis-Ribeiro<sup>b</sup>

<sup>a</sup>Department of Gastroenterology, Hospital de Egas Moniz, Centro Hospitalar Lisboa Ocidental, Lisbon, and  
<sup>b</sup>Department of Gastroenterology, Instituto Português de Oncologia, Porto, Portugal



**Fig. 2.** Examples of systematic imaging in upper GI endoscopy. **a** Proximal esophagus; **b** distal esophagus; **c** Z-line and diaphragm indentation; **d** cardia and fundus on retroflexed view; **e** body (including lesser curvature) on retroflexed view; **f** body on retroflexed view; **g** angulus on partial retroflexion; **h** antrum; **i** duodenal bulb; **j** second part of the duodenum, including the ampulla.

# Create your own process and document

- Define a quality enhanced visual inspection system
  - Ability to capture still pictures
  - Ability to capture video
  - Store/log/reference these images
  - Have a viewing screen (live)
  - Have a reference screen
  - Cleaning and sterilization for the inspection tool
  - Vendor partner who has experience in this area
  - Training and competency for staff
- In the United States
- "In court, the medical record is the care rendered," they say. "Jurors view good record keeping as an indicator of good care — poor documentation can create an aura of poor care and damage the credibility of the healthcare providers."
- Thus, if it wasn't documented, it wasn't done.
- Record your findings of your inspection
  - Not all inspection scopes allow you to do this
- Protect yourself

<http://www.outpatientsurgery.net/surgical-facility-administration/avoid-medical-malpractice/how-to-survive-a-med-mal-suit-orx-proceedings-13?utm-source=tod&utm-medium=email&utm-campaign=tips>



What's in your department?

*“Subtle instrument failures can have dramatic impact on surgical outcomes. Broken scissors can leave behind fragments inside patients, unfinished edges on a ribbon retractor can result in torn vessels, and hidden bioburden can result in infections. Failures in sterile processing have a direct impact on patient outcomes and it is critical that leadership give technicians every tool necessary to perform at the highest level”.*

<https://hpnonline.com/new-age-visual-inspection/>

Your facility should look like this:



# Visual Inspection

- Takes place every time you touch an instrument
- Many methods to inspect and enhance the visual inspection process within a CSSD area
  - Your natural eyesight
  - Lamp magnifier
  - Handheld magnifier
  - Borescope (Flexible Inspection Scope)
  - USB computer-based microscope
- QA Tray Quality – Post Production
- Work with a quality partner who has a track record in this area
- Create your own library of pictures
- Document your results (PQ)
- Visual inspection is a way to help verify that you are doing it right each time (PQ)
- Remember if it is dirty you need to re-clean it. If it is not functionally correct, or if it is damaged, take it out of service.

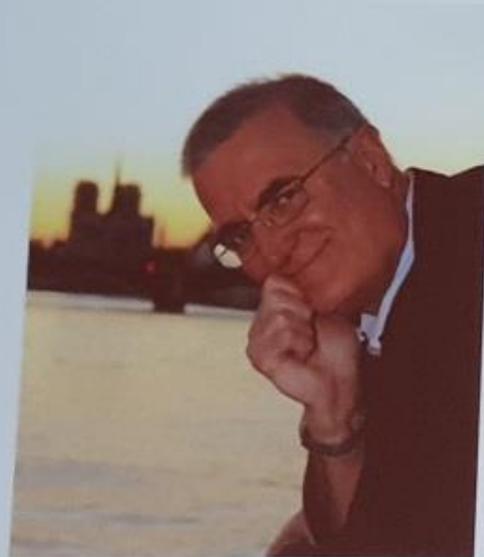
## Why close with this quote?

***“We cannot force someone to hear a message they are not ready to receive.***

***But we must never underestimate the power of planting a seed.”***

- We wish to influence other people and make them understand something that we believe to be important.
- But, no matter how hard we try, we cannot *force* people to comprehend and accept what we're telling them. No matter how much we'd like to, we cannot force them to understand. We cannot force them to change. We cannot force them to grow.
- Even so, we *can* plant seeds. We can do our best to communicate the message firmly but kindly — planting that seed of thought. And then do our best to nurture that seed, patiently waiting and hoping for growth. While there's no guarantee of a seed we plant ever sprouting and growing, there's absolutely *no* chance of a harvest if the seed is never planted!
- That is why we educate.
- Let us all keep sharing those seeds of wisdom and knowledge with each other.
- Thank you for accepting my presentation to speak at this year's meeting on this topic.

## Contact Information



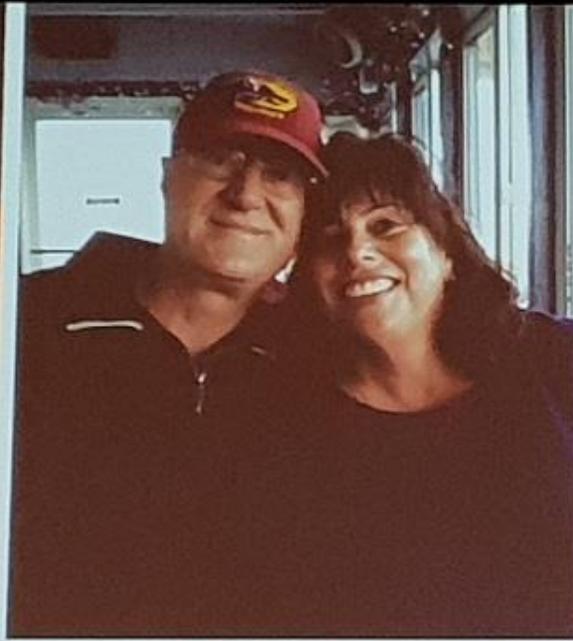
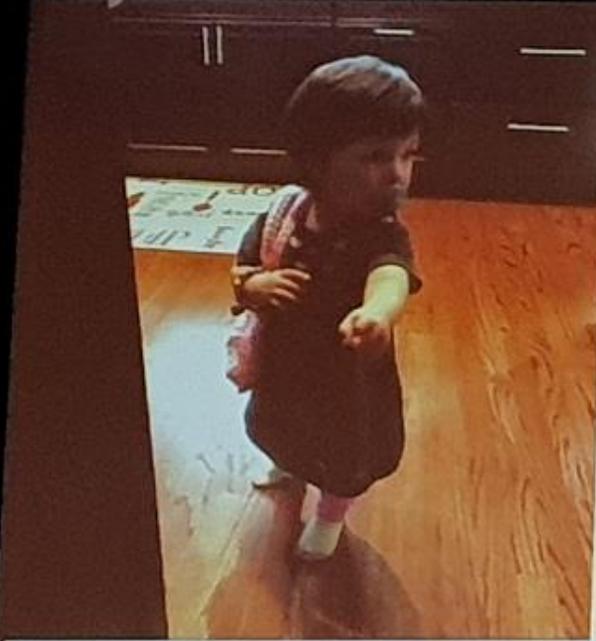
Stephen M. Kovach  
1-800-521-6224/Ext.6621  
[cpdguy@hmark.com](mailto:cpdguy@hmark.com)  
[www.cpdguy.net](http://www.cpdguy.net)  
[www.hmark.com](http://www.hmark.com)

Some say that knowledge is power,  
but I say the real power is  
when you share your  
knowledge with others.  
Please share the knowledge  
you gained today with others  
where you work.

**Keep this in your thoughts;  
you are doing amazing things  
right now. Build on that  
success to make change  
where change needs to be  
made.**



**Thank you to the  
committee for the  
opportunity to present at  
this meeting. Enjoy the  
rest of the meeting and  
safe travels home.**



This is why we do what we do...it could be our family having the procedure...Thank you .

