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A Getinge company

Impacts of The Latest ANSI? AAMI St91 Standards in the Reprocessing Space.

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Disclosures

- I am an employee of Healthmark Industries Fraser, Michigan USA – a manufacturer and distributor of medical products to healthcare facilities and healthcare professionals.
- No compensation has been received for this presentation
- All opinions are those of the presenter.
- This 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

- Overview of the difference between regulations, standards, and recommendations
- Update on most current guidelines for endoscope processing.
- Review of latest hot topics in endoscope processing.

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Regulations, Standards, and Recommendations

Regulations/Standards/Guidelines – U.S.

- **Regulations**
  - A rule or directive made and maintained by an authority
  - Mandatory

  *Sheppard's Pie
- **Standards**
  - Requirements and specifications to ensure consistency and fit for purpose
  - Voluntary, but can become mandatory

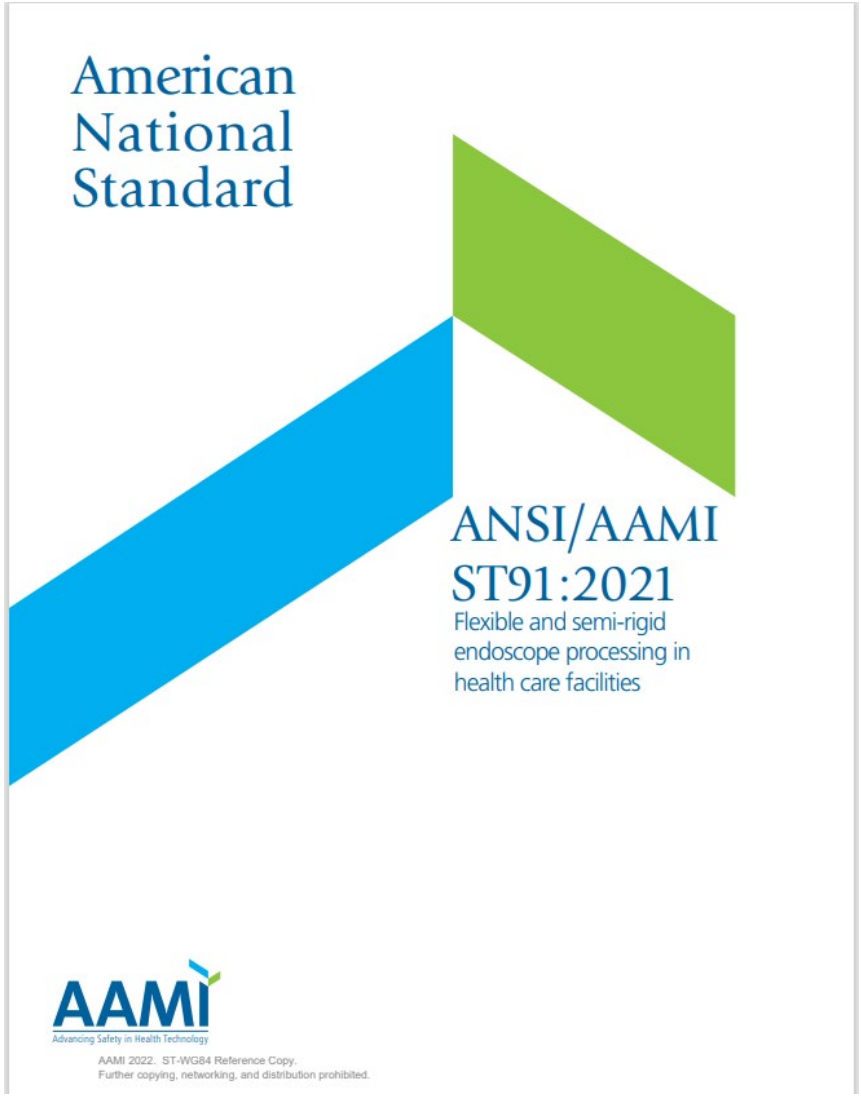
  *Recipe
- **Guidelines, Recommended Practices, Technical Information reports**
  - Technical guidance, information or preferred procedures regarding a given topic
  - Voluntary but with interpretation

  *Ingredients

What are standards & guidelines based on?

- All the major groups support in principle
  - Quality improvement
  - Quality assurance
  - Monitoring of processes
- Clinically relevant & evidence-based practices
- Peer reviewed literature
- Other articles and research.
- Manufacturer's IFUs
- **This is, and has been, a dynamic process**

ANSI/AAMI ST 91



- Flexible and semi-rigid endoscope reprocessing in health care facilities
- Contains best practices for endoscope reprocessing in ANY setting
- Excludes TEE/ultrasound probes
- Should, Shall, & Must

Should-recommended
Shall-strictly to be followed to conform to standard
Must-unavoidable

TIR 99 – Reprocessing of Ultrasound Probes and Dilators

- TEE Probes, Vaginal Probes, Rectal Probes, and Dilators
- Potential to expand to other relevant accessories and devices such as manometry probes

https://www.fda.gov/medical-devices/medical-device-safety/safety-communications

Safety Communications

- 2020 Safety Communications
- 2019 Safety Communications
- 2018 Safety Communications
- 2017 Safety Communications

The FDA posts Medical Device Safety Communications to describe FDA's analysis of a current issue and provide specific regulatory approaches and clinical recommendations for patient management.

The most recent safety communications are listed by year in the left navigation. Older safety communications are listed below.

Content current as of:
09/26/2018

Older Safety Communications

- 2016 Safety Communications
- 2015 Safety Communications
- 2014 Safety Communications
- 2013 Safety Communications
- 2012 Safety Communications
- 2011 Safety Communications
- Safety Communications Issued Prior to 2011

MAUDE
stands for
Manufacturer And User facility Device Experience database

Subscribe to Medical Device Safety and Recalls
Sign up to receive email updates on medical device recalls, safety communications, and other

Email Address | Subscribe

https://www.fda.gov/medical-devices/medical-device-safety/safety-communications

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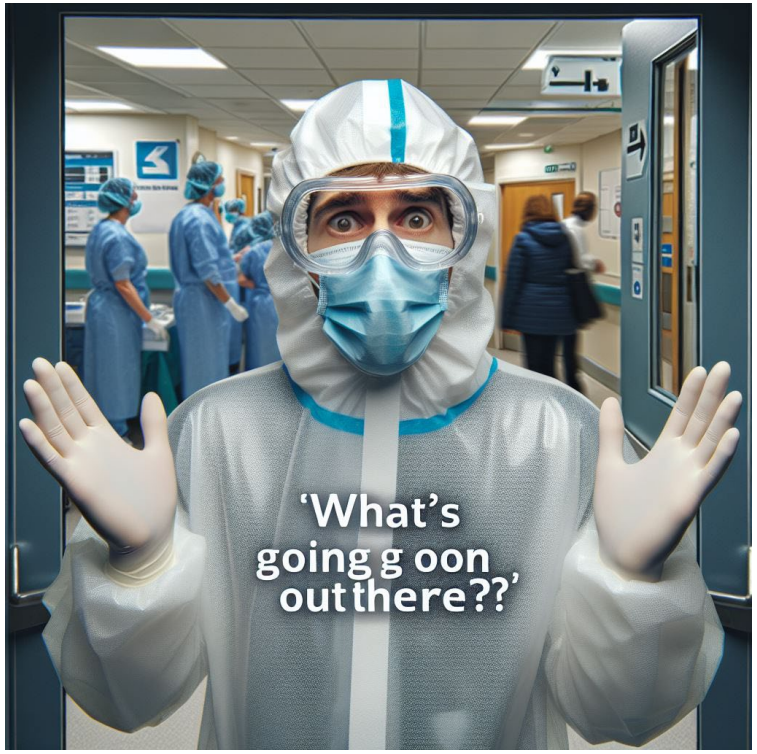
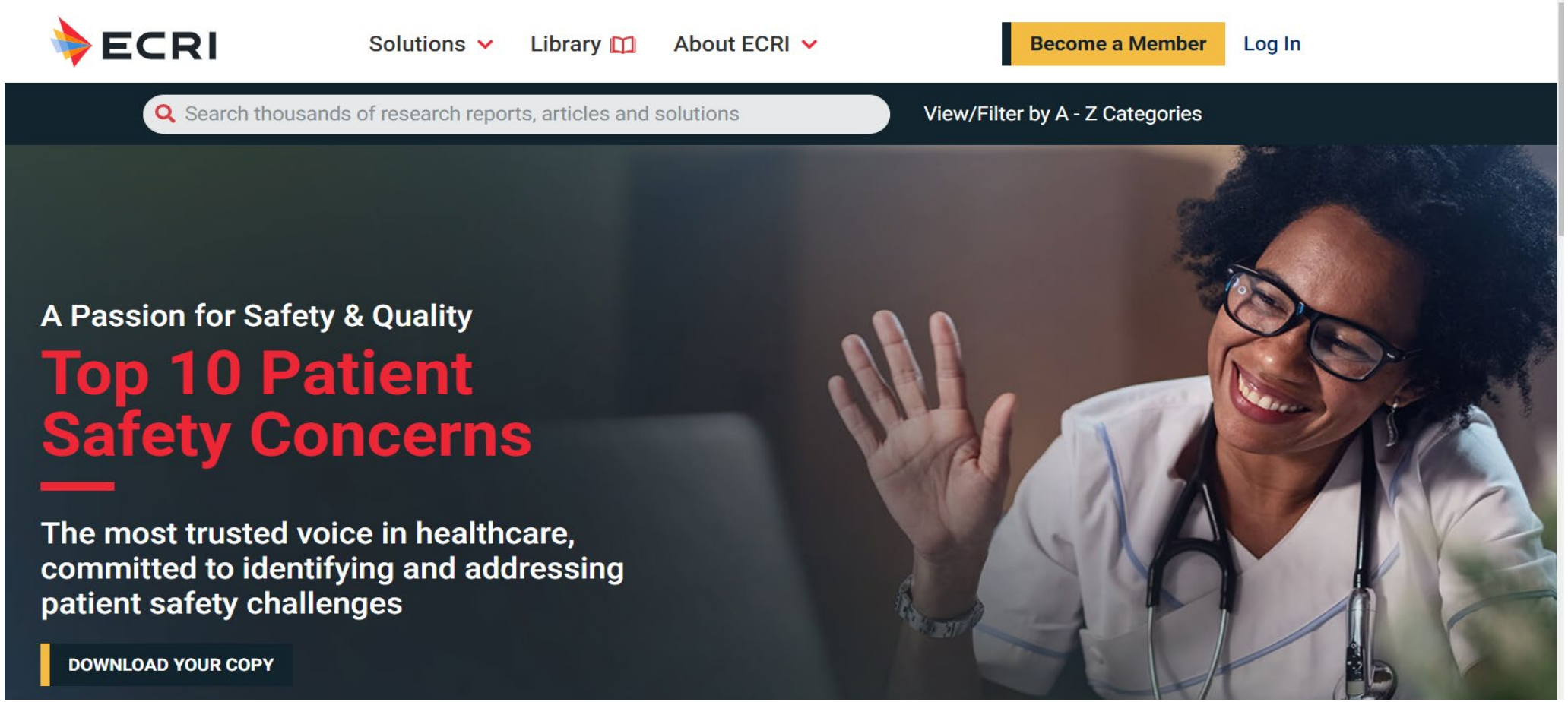
What's Going on Out There?

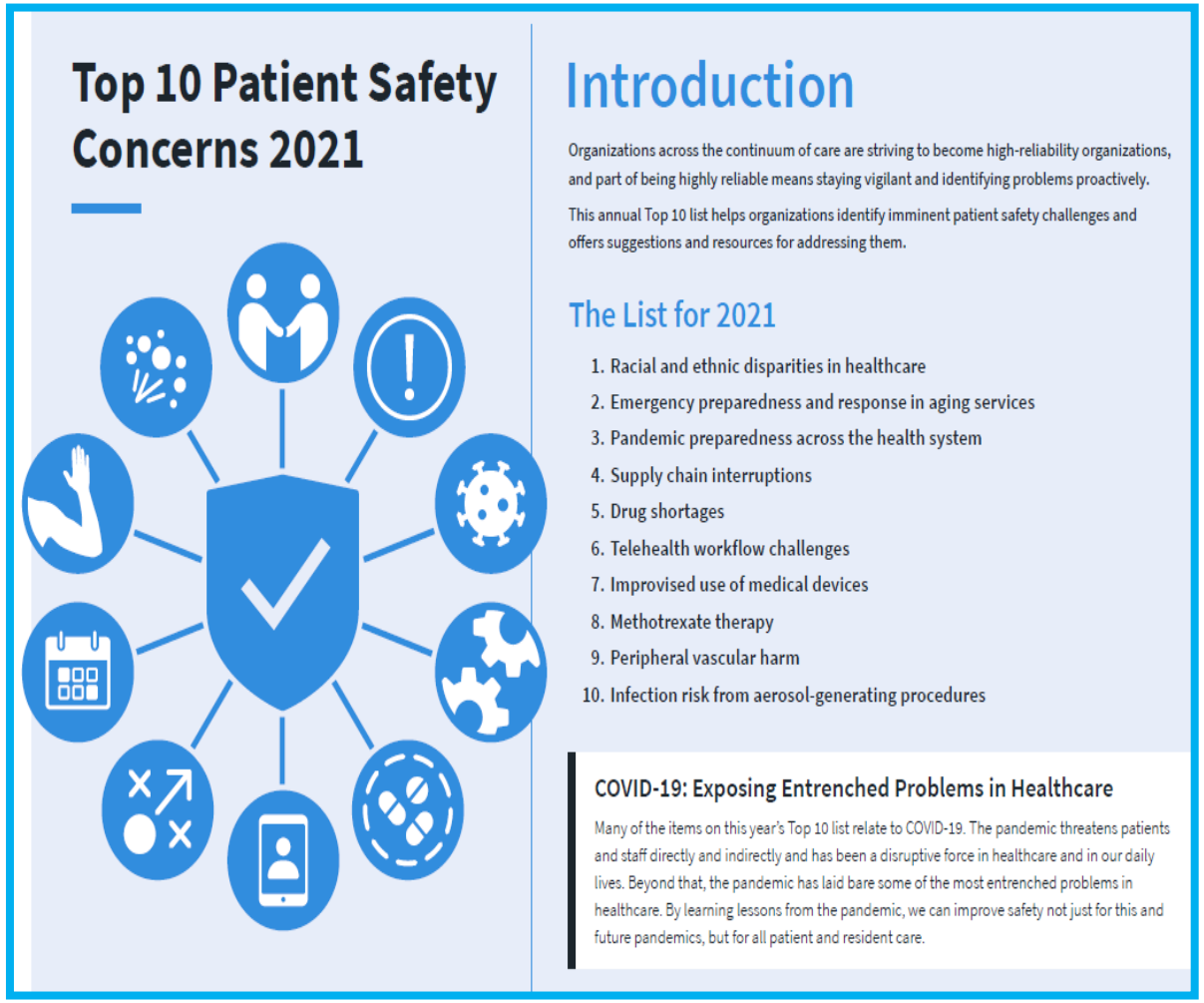




ECRI is an independent, nonprofit organization improving the safety, quality, and cost-effectiveness of care across all healthcare settings worldwide.

https://www.ecri.org/

- 2018 –
  - #2 - Endoscope Reprocessing Failures Continue to Expose Patients to Infection Risk
- 2019 –
  - #5 - Mishandling Flexible Endoscopes after Disinfection Can Lead to Patient Infections
- 2020 –
  - #4 - Responding to and Learning from Device Problems
  - #5 - Device Cleaning, Disinfection, and Sterilization
  - #6 - Standardizing Safety across the System
- **2021 -**
  - **#3 - Pandemic preparedness across the health system**
  - **#4 - Supply chain interruptions**
  - **#10 - Infection risk from aerosol-generating procedures**



Top 10 Patient Safety Concerns 2021

Introduction

Organizations across the continuum of care are striving to become high-reliability organizations, and part of being highly reliable means staying vigilant and identifying problems proactively.

This annual Top 10 list helps organizations identify imminent patient safety challenges and offers suggestions and resources for addressing them.

The List for 2021

1. Racial and ethnic disparities in healthcare
2. Emergency preparedness and response in aging services
3. Pandemic preparedness across the health system
4. Supply chain interruptions
5. Drug shortages
6. Telehealth workflow challenges
7. Improvised use of medical devices
8. Methotrexate therapy
9. Peripheral vascular harm
10. Infection risk from aerosol-generating procedures

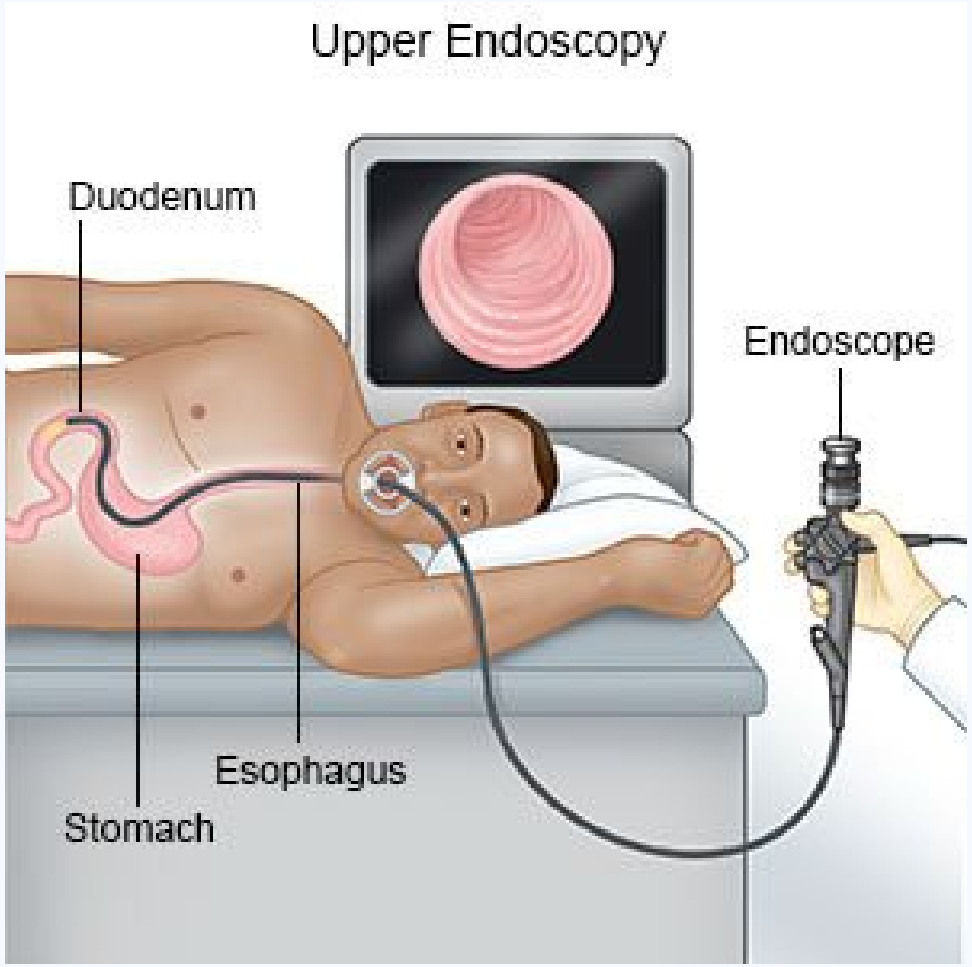
COVID-19: Exposing Entrenched Problems in Healthcare

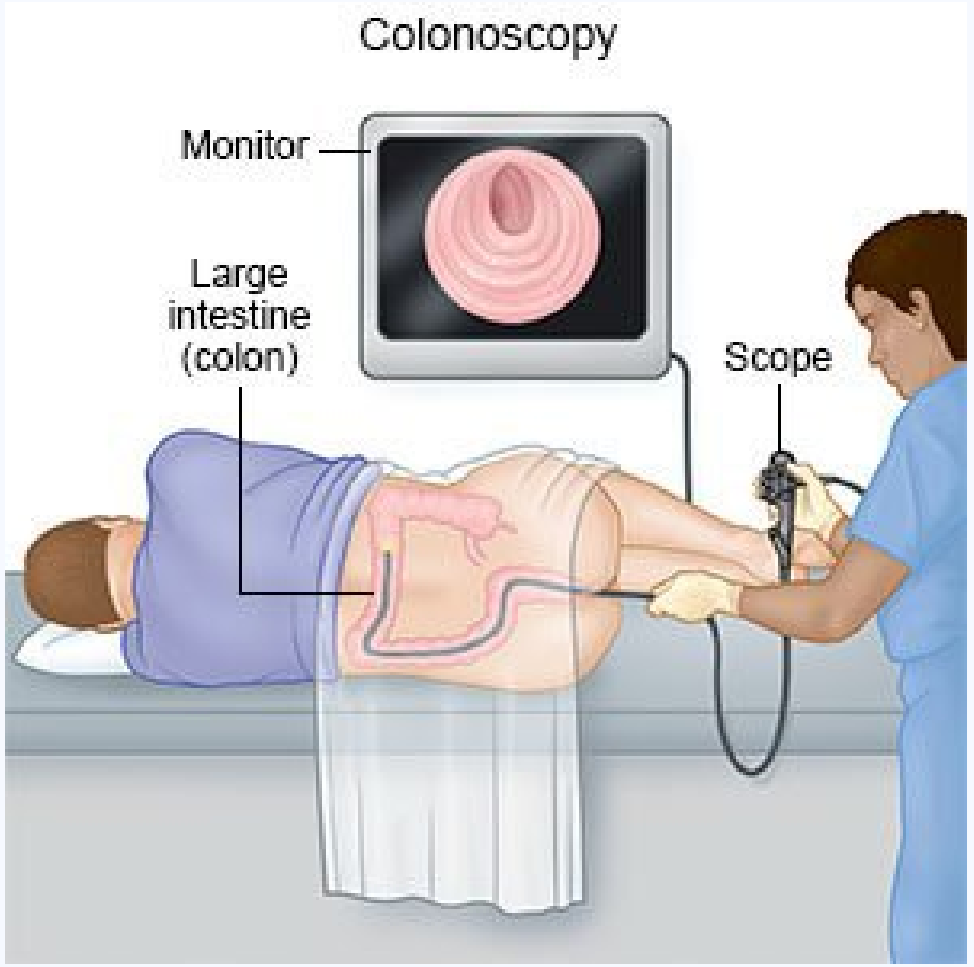
Many of the items on this year's Top 10 list relate to COVID-19. The pandemic threatens patients and staff directly and indirectly and has been a disruptive force in healthcare and in our daily lives. Beyond that, the pandemic has laid bare some of the most entrenched problems in healthcare. By learning lessons from the pandemic, we can improve safety not just for this and future pandemics, but for all patient and resident care.

Many Types of Flexible Endoscopes

root	anatomical target(s)	example scopes	example procedure titles	example Olympus scope models
Gastro	esophagus, stomach, duodenum	Gastroscopes	Upper Endoscopy, Gastroscopy, Esophagogastroduodenoscopy (EGD), Endoscopic Ultrasound (EUS), Percutaneous Endoscopic Gastrostomy (PEG)	GIF-H180J, GIF-XP190N, GIF-HQ190, GF-UC140P-AL5
Colono	colon	Colonoscopes	Colonoscopy, Lower Endoscopy	CF-HQ190L, PCF-H190L
Duodeno	ampulla, bile duct, pancreatic duct	Duodenoscopes	Endoscopic retrograde cholangiopancreatography (ERCP)	TJF-Q190, TJF-Q180V
Entero	small intestine	Enteroscopes	Small Bowel Enteroscopy (SBE), Balloon Enteroscopy	SIF-Q180
Broncho	lungs	Bronchoscopes	Bronchoscopy, Endobronchial Ultrasound (EBUS)	BFXP60, BF-Q190, BF-UC180F
Uretero	urethra, bladder	Uretroscopes	Ureteroscopy	URF-V, URF-P6
Cysto	bladder	Cystoscopes	Cystoscopy	CYF V2, CYF-5, CYF-VH
Hystero	uterus	Hysteroscopes	Hysteroscopy	HYF-V, HVY-XP
Laryno	upper airway, vocal cords	Rhinolaryngoscopes	Rhinoscopy, Laryngoscopy	ENF-V3, ENF-VH

EGD (esophagogastroduodenoscopy)

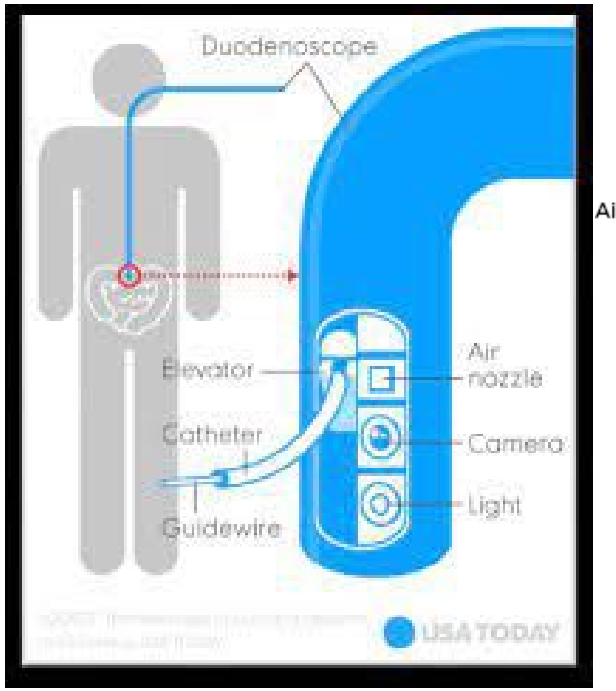


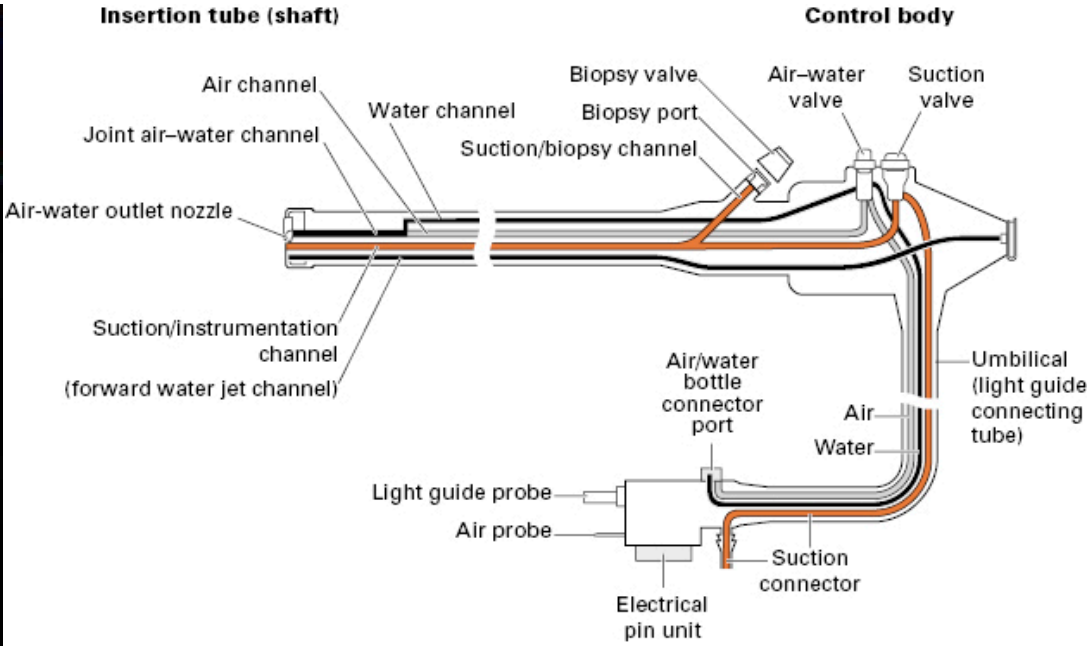


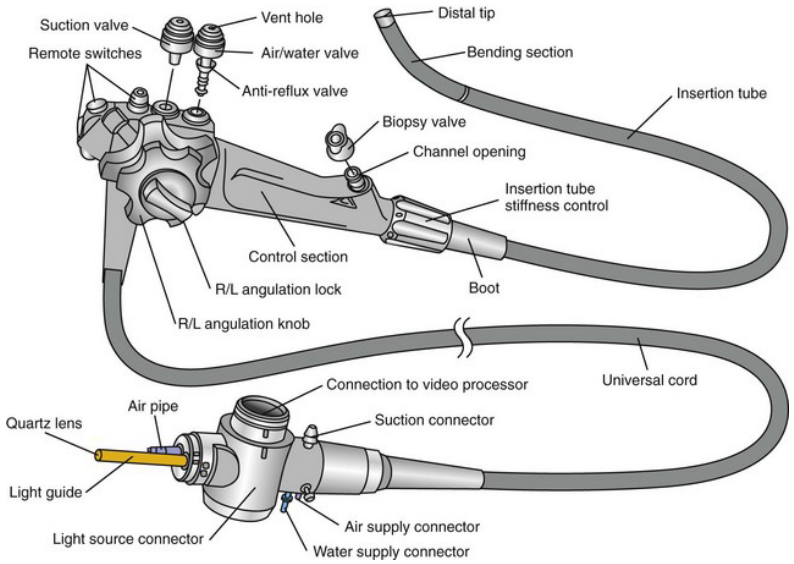
Anatomy of Scope

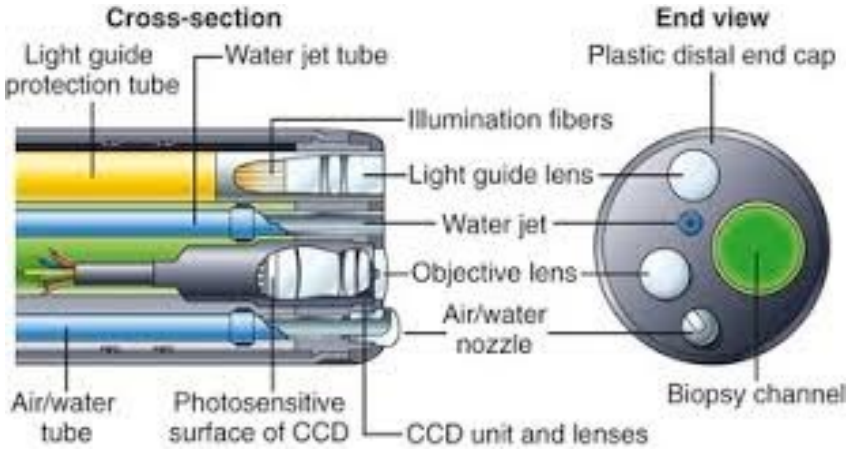
-The complexity of the scope's anatomy makes cleaning flexible endoscopes extremely difficult. Contributes to improper cleaning.

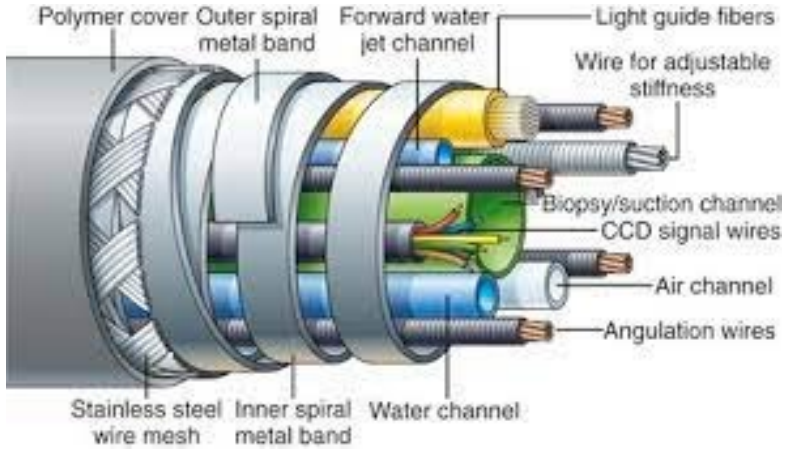
-Extremely fragile











FDA Safety Communications

The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication – August 29, 2019

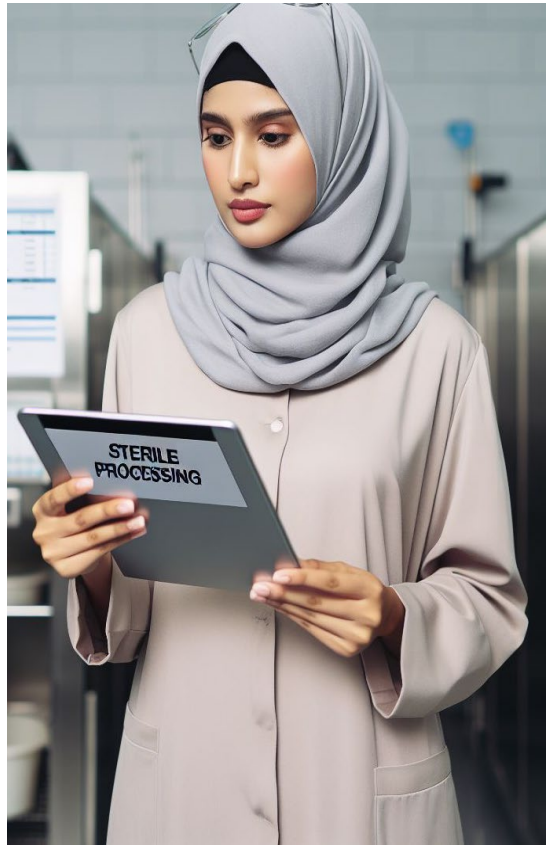
https://www.fda.gov/medical-devices/safety-communications/fda-recommending-transition-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication?utm_campaign=2019-08-29%20CDRH%20Safety%20Comm%20-%20%20Recommendations%20and%20Updates%20to%20Help%20Improve%20Duodenoscope%20Reprocessing&utm_medium=email&utm_source=Eloqua

- "Now recommending that hospitals and endoscopy facilities transition away from fixed endcap duodenoscopes to those with newer design features that facilitate or eliminate the need for reprocessing.
- Consider using duodenoscopes that have disposable components, if available.
- Ensure staff are meticulously following reprocessing instructions.
- Institute a quality control program that includes sampling and microbiological culturing, and other monitoring methods.
- Develop schedules for routine inspection and periodic maintenance in accordance with the duodenoscope manufacturer's instructions."

522 Postmarket Surveillance studies

Section 522 of the Act (21 U.S.C. § 360l) authorizes FDA to require postmarket surveillance on Class II or Class III medical devices

- **Jan 2015- July 2019** a total of **79** duodenoscope death reported. **76** of the deaths were associated with duodenoscope models marketed in the U.S. In 76 death reports involving duodenoscope models cleared in the U.S., **67** of the deaths occurred in the U.S.



- In October 2015, the **FDA ordered each U.S. duodenoscope manufacturer** (Olympus, Fujifilm and Pentax) to conduct postmarket surveillance studies ("522 study") to better understand how these devices are reprocessed in **real-world settings** and their impact on duodenoscope transmitted infections.
- On December 10, 2018, the **FDA issued a Safety Communication** to provide interim results from the ongoing mandated postmarket surveillance studies of duodenoscopes reprocessing. Interim results from the ongoing postmarket surveillance studies indicate higher than expected contamination rates after duodenoscope reprocessing.

522 Study Results

Human Factors Study Question

- Human factors study results indicate that reprocessing instructions in current user manuals are **difficult for reprocessing staff** to comprehend and follow.
- The study revealed that the **descriptions** of some of the processing steps in the user manuals were **unclear.**

Sampling and Culturing Study Questions:

At least 10% of the samples have been collected for the Sampling and Culturing studies. The studies were designed **assuming less than a 0.4% contamination rate.**

- Interim results from these studies indicate higher-than-expected contamination rates after reprocessing, with up to 3% of properly collected samples testing positive for enough low concern organisms to indicate a reprocessing failure and **up to 3%** of properly collected samples testing positive **for high concern organisms** (*E. coli*, and *Pseudomonas aeruginosa)*. Some factors that may contribute to device contamination after reprocessing include device damage and errors in reprocessing.

Semi-Final Report- Grater then 9%

522 Postmarket Surveillance studies

U.S. FOOD & DRUG ADMINISTRATION

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FDA NEWS RELEASE

FDA warns duodenoscope manufacturers about failure to comply with required postmarket surveillance studies to assess contamination risk

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More Press Announcements

For Immediate Release: March 09, 2018

The U.S. Food and Drug Administration today issued warning letters to all three duodenoscope manufacturers for failing to comply with requirements of federal law under which they were ordered to conduct postmarket surveillance studies to assess the effectiveness of reprocessing the devices.

As part of an ongoing effort to prevent patient infections associated with the transmission of bacteria from contaminated duodenoscopes, the FDA in 2015 ordered U.S. duodenoscope manufacturers Olympus, Fujifilm and Pentax to conduct a postmarket surveillance study to determine whether healthcare facilities were able to properly clean and disinfect the devices. Specifically, as part of their approved study plans, all three manufacturers are required to conduct a study to sample and culture reprocessed duodenoscopes that are in clinical use to learn more about issues that contribute to contamination, as well as a human factors study to assess how well trained hospital staff are following the reprocessing instructions.

Content current as of:
03/09/2018

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Infections Associated with Reprocessed Urological Endoscopes - Letter to Health Care Providers

Letters to Health Care Providers

April 1, 2021

The U.S. Food and Drug Administration (FDA) wants to raise awareness among health care providers, including those working in reprocessing units in health care facilities, about the risk of infections associated with reprocessed urological endoscopes, including cystoscopes, ureteroscopes, and cystourethroscopes, used for viewing and accessing the urinary tract. The FDA has received numerous Medical Device Reports (MDRs) which describe patient infections post procedure or other possible contamination issues associated with reprocessing these devices.

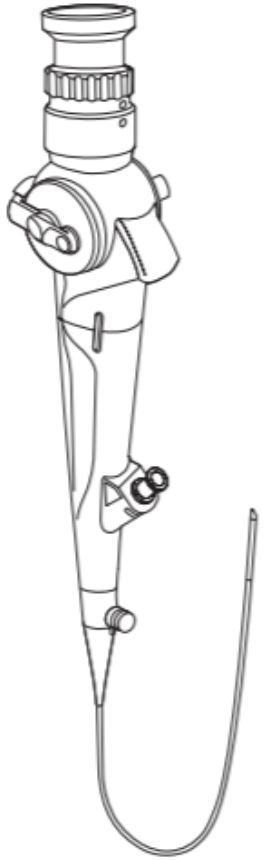
The FDA is currently investigating the potential causes and contributing factors associated with the reported infections and contamination issues. While some reports indicate

Content current as of:
04/01/2021

Regulated Product(s)
Medical Devices

Revised labelling for Olympus URF-P6, URF-P6R, V, V2, V2R

- Ureteroscope recall
- Olympus new manuals and letter dated 1/17/18
  - Scope tips can break off in patient
  - Also changed reprocessing instructions
    - Requires sterilization!
    - Removed HLD info
    - Inspection required prior to use



Residual Moisture in Scopes

Ofstead and Associates performed a multisite study which was published in AJIC in 2018

Results:

- Fluid was detected in 22 of 45 (**49%**) endoscopes.
- High adenosine triphosphate (ATP) levels were found in **22%** of endoscopes
- Microbial growth was detected in **71%** of endoscopes.
- Retained fluid was associated with significantly higher ATP levels ($P < .01$).
- Reprocessing and drying practices conformed with guidelines at 1 site and were substandard at 2 sites.
- Damaged endoscopes were in use at **all** sites.

Conclusions: Inadequate reprocessing and insufficient drying contributed to retained fluid and contamination found during this multisite study.

Importance of Drying Continue

Study by Perumpail et al in 2019 published in the AJIC resulted in the following:

- **Automated** drying and storage cabinet= **dry internal** channels at **1 hour** & **external** surfaces at **3 hours** in **all** endoscopes.
- **Standard** storage cabinet= residual **internal fluid** at **24 hours** & **external** surfaces were **dry** at **24 hours**.

Colony Forming Unit Growth		
Scope	Automated	Standard
bronchoscopes	$P = .02$	8.1×10^6 per hour
colonoscopes	$P = .01$	8.3×10^6 per hour
duodenoscopes	$P = .02$	7.0×10^7 per hour

Conclusions: An automated cabinet is advantageous for rapid drying of endoscope surfaces and in reducing the risk of microbial growth post-reprocessing.

Additional Studies

Ofstead et al. (2016)	Ofstead et al. (2017)	Thacker et al. (2018)	Barakat et al. (2018)	Nerandzic et al. (2020)
• Gastroscopes more contaminated than colonoscopes • Biopsy and suction ports, dirties areas	• Simethicone • Dangers of Silkspray • 85% scopes evaluated needed to be sent for repair	• 86% Internal scratches • 23% Intrachannel debris • 28% Moisture after storage, no dry time	• 99% scratches • 77% attached peelings • 96% minor debris • 43% residual fluid	• Alcohol flush followed by hanging ambient cabinet not effective • Channel drying-channel dependent • Some channels alcohol increased drying time

Fluid retention in endoscopes: A real-world study on drying effectiveness

Cori L Ofstead [1], Krystina M Hopkins [2], Aaron L Preston [3], Charesse Y James [4], Jill E Holdsworth [3], Abigail G Smart [2], Larry A Lamb [2], Kari L Love [5]

Affiliations + expand

PMID: 38408542 DOI: 10.1016/j.ajic.2024.02.015

Free article

Abstract

Background: Outbreaks linked to inadequate endoscope drying have infected numerous patients, and current standards and guidelines recommend at least 10 minutes of forced air for drying channels. This study evaluated a new forced-air drying system (FADS) for endoscopes.

Methods: Drying was assessed using droplet detection cards; visual inspection of air/water connectors, suction connectors, and distal ends; and borescope examinations of endoscope interiors. Assessments were performed after automated endoscope reprocessor (AER) alcohol flush and air purge cycles and after 10-minute FADS cycles.

Results: Researchers evaluated drying during encounters with 22 gastroscopes and 20 colonoscopes. After default AER alcohol and air purge cycles, 100% (42/42) of endoscopes were still wet. Substantial fluid emerged from distal ends during the first 15 seconds of the FADS cycle, and droplets also emerged from air/water and suction connectors. Following FADS cycle completion, 100% (42/42) were dry, with no retained fluid detected by any of the assessment methods.

Conclusions: Multiple endoscope ports and channels remained wet after AER cycles intended to aid in drying but were dry after the FADS cycle. This study reinforced the need to evaluate the effectiveness of current drying practices and illustrated the use of practical tools in a real-world setting.

OFSTEAD & associates

Results: Researchers evaluated drying during encounters with 22 gastroscopes and 20 colonoscopes. After default AER alcohol and air purge cycles, 100% (42/42) of endoscopes were still wet. Substantial fluid emerged from distal ends during the first 15 seconds of the FADS cycle, and droplets also emerged from air/water and suction connectors. Following FADS cycle completion, 100% (42/42) were dry, with no retained fluid detected by any of the assessment methods.

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Out With The Old and In With The New

New AAMI ST91:2021

Flexible and semi-rigid endoscope processing in health care facilities

Highlights

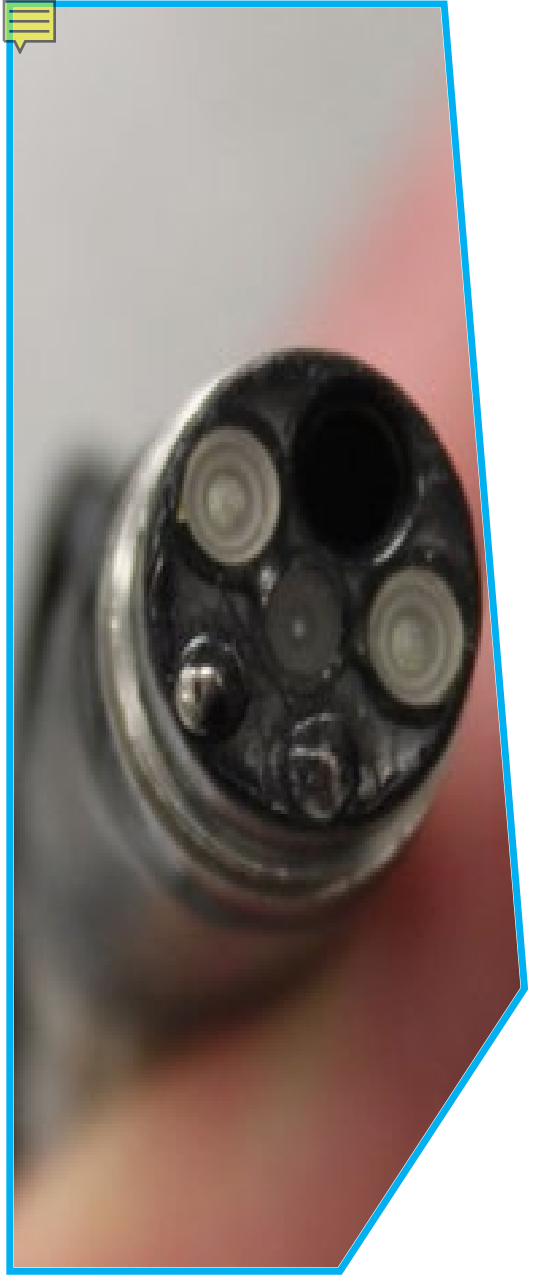
Point of Use Treatment

- Note the **time of point of use treatment completed** and convey that info to processing staff
  -Labels available
- Any delay and/or failure to perform point of use treatment, processed using delayed processing protocols described in IFUs
  -Typically, 1hour window

AAMI ST91:2021
Section 7.2

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”



Endoscope Visual Inspection

AAMI ST91:2021 Annex E

- Unaided eye and enhanced visual inspection tools
- Color photos
- 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
- AAMI and AORN recommend use of a borescope for internal inspection

AAMI ST91:2021
Section 7.8.2

FDA/CDC distal end 5x magnification and duodenoscope 10x

BASIC visual inspection - the UNAIDED eye

- The most basic verification of the performance of a cleaning process is by carefully inspecting the cleanliness of devices 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.

Standards & Guidelines -

- AAMI - ST79 and ST91
- AORN
- SGNA

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

Enhanced visual inspection

- “Magnifiers and borescopes are used to inspect where the unaided eye cannot see, including assessments for defects in functionality, damage, staining, missing components, … moisture in or on the endoscope.

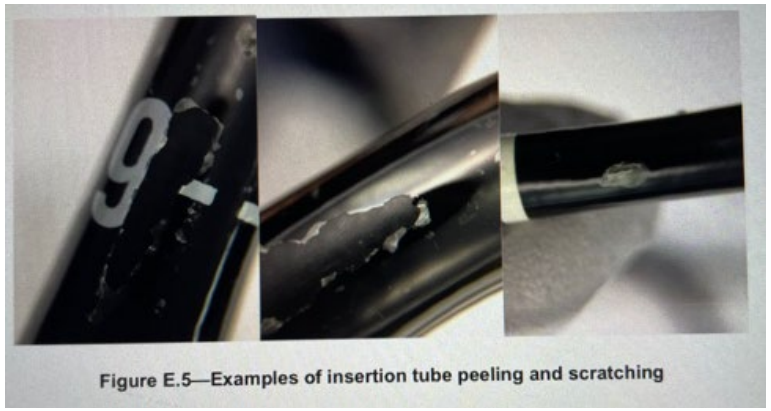
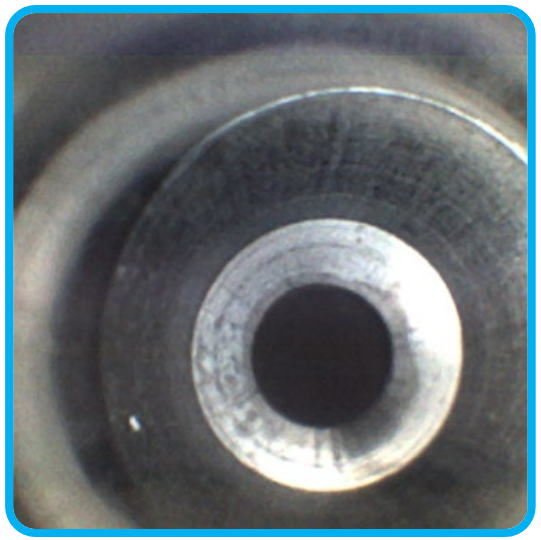


Figure E.5—Examples of insertion tube peeling and scratching



New biopsy area

- Used in major research papers highlighting gaps in flexible endoscope processing
- Not required in any endoscope IFUs at this time.

Manufacturer support of enhanced inspection is occurring

OLYMPUS

October 21, 2019

Olympus Communication

The Use of Borescopes to Inspect Channels of Olympus Flexible Endoscopes

Olympus is aware that several industry guidelines have recommendations regarding the use of borescopes and that facilities may choose to incorporate the use of borescopes into their internal standards or practices. In an effort to support our customers who choose to use borescopes to inspect the channels of their Olympus flexible endoscopes, this document offers a general overview of some phenomena that may be observed during borescope inspection.

The use of borescopes to inspect flexible endoscopes is within the discretion of each specific facility based upon its own judgment and personnel. Please refer to the Instructions for Use for each specific endoscope model at your facility for validated reprocessing instructions. Olympus neither requires nor prohibits the use of borescopes as a tool for visual inspection of flexible endoscopes. The benefits of using borescopes to inspect endoscopic channels is still being discussed among scientific experts[1-3] and knowledge is still limited.

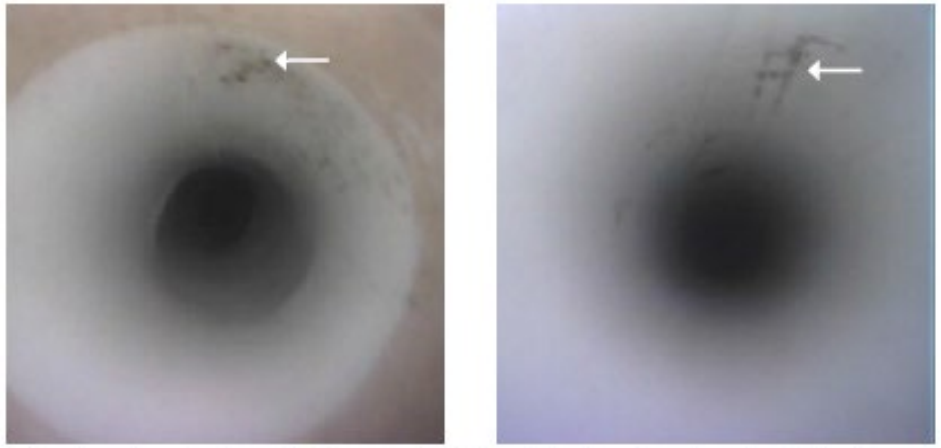
The images within this document are depictions of normal channels that may be encountered during the borescope evaluation process. Please note that Olympus endoscopes contain multiple varieties of instrument channels that may have differing appearances when viewed through a borescope. In addition, images may differ among makes and models of borescopes.

If you view something other than what is depicted in this letter, you may elect to send the endoscope into Olympus for evaluation. Please note that Olympus service evaluations do not include borescope inspections unless specifically requested.

October 21, 2019

The Use of Borescopes to Inspect Channels of Olympus Flexible Endoscopes

Black Spots or Marks

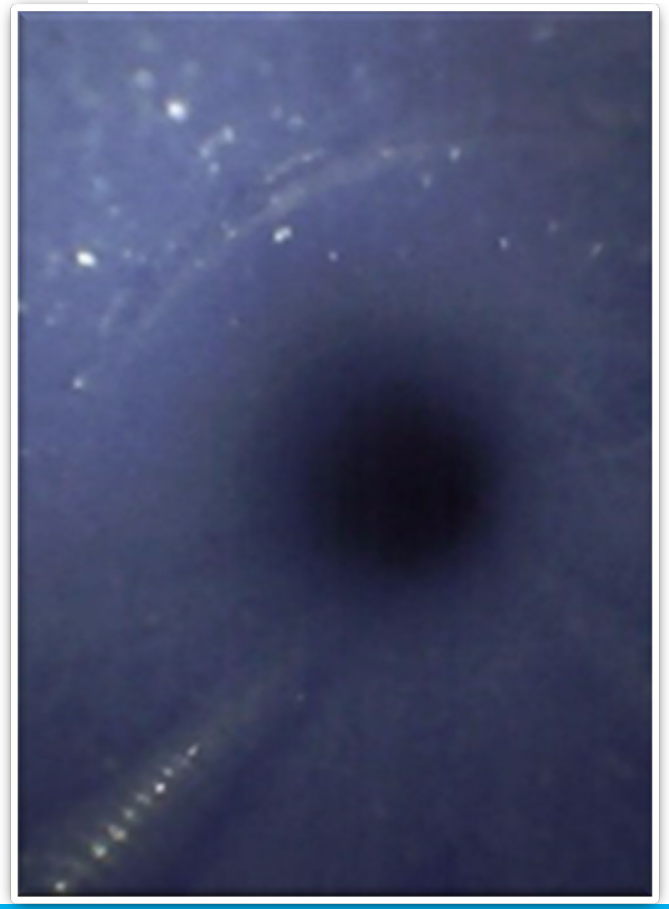


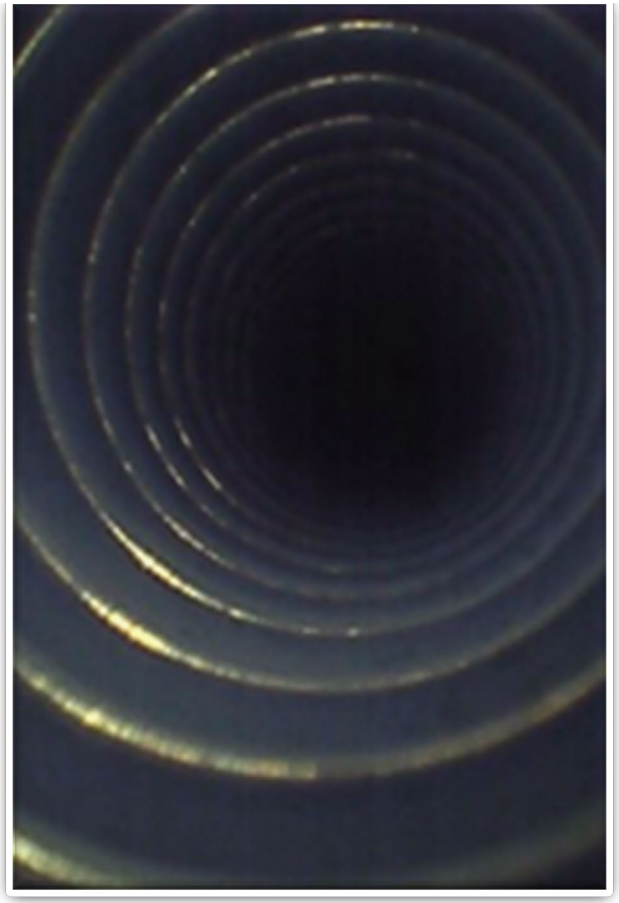
Black spots or marks may be observed on the inner surface of the instrument channel. Two circumstances when this observation is expected are when the endoscope is newly purchased, and after an Olympus-performed repair which included a channel replacement.

Certain materials used in the endoscope manufacturing and repair processes may create these black spots/marks. Their presence is considered to be a normal condition of the channel when observed after one of these processes has been performed.

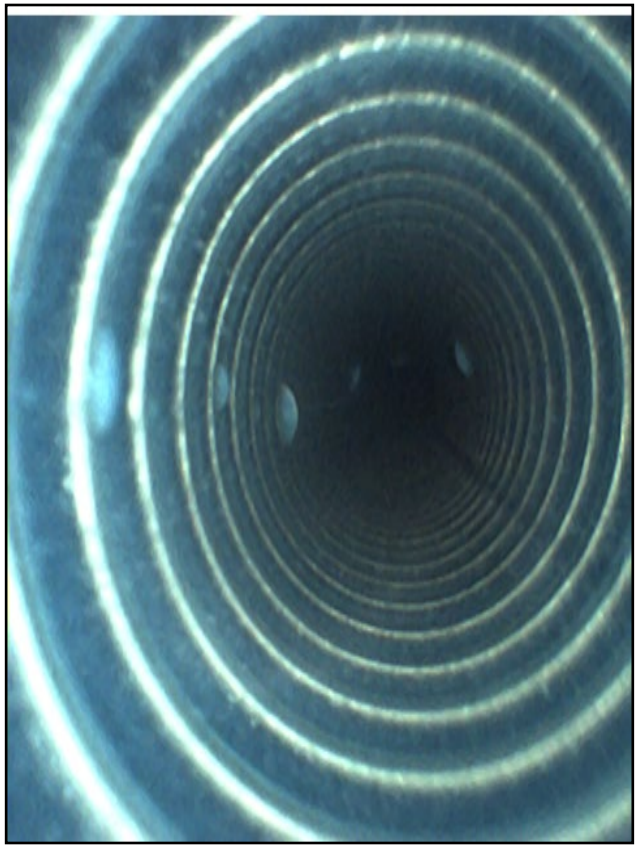
"Certain materials used in endoscope manufacturing and repair processes may create these black spot/marks"

Let's start with what internal channels should look like

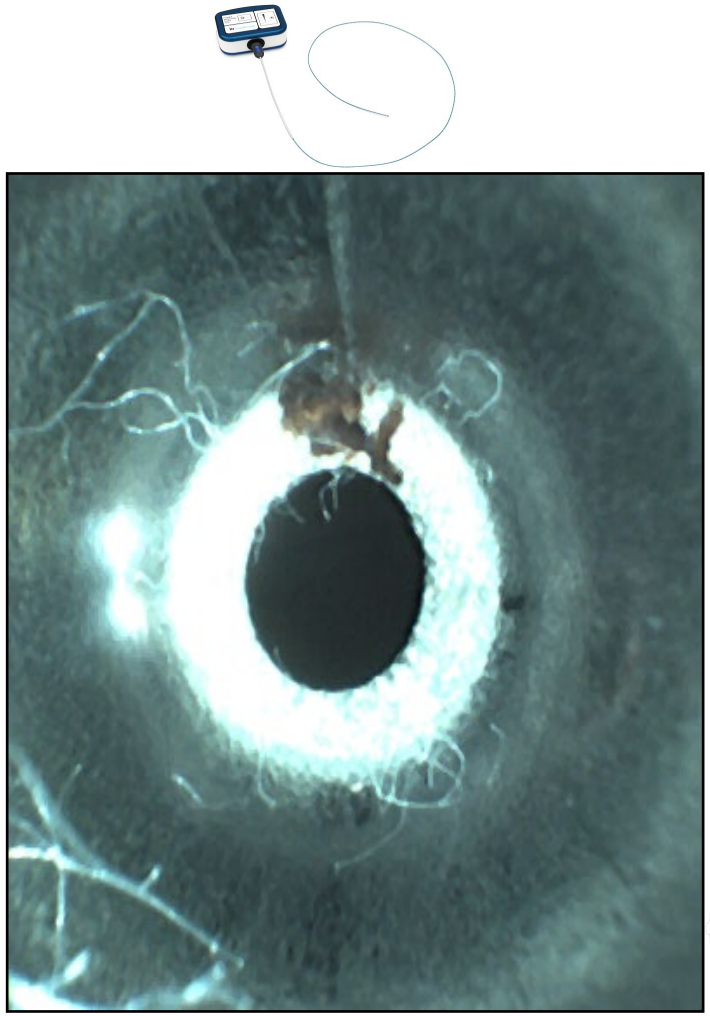




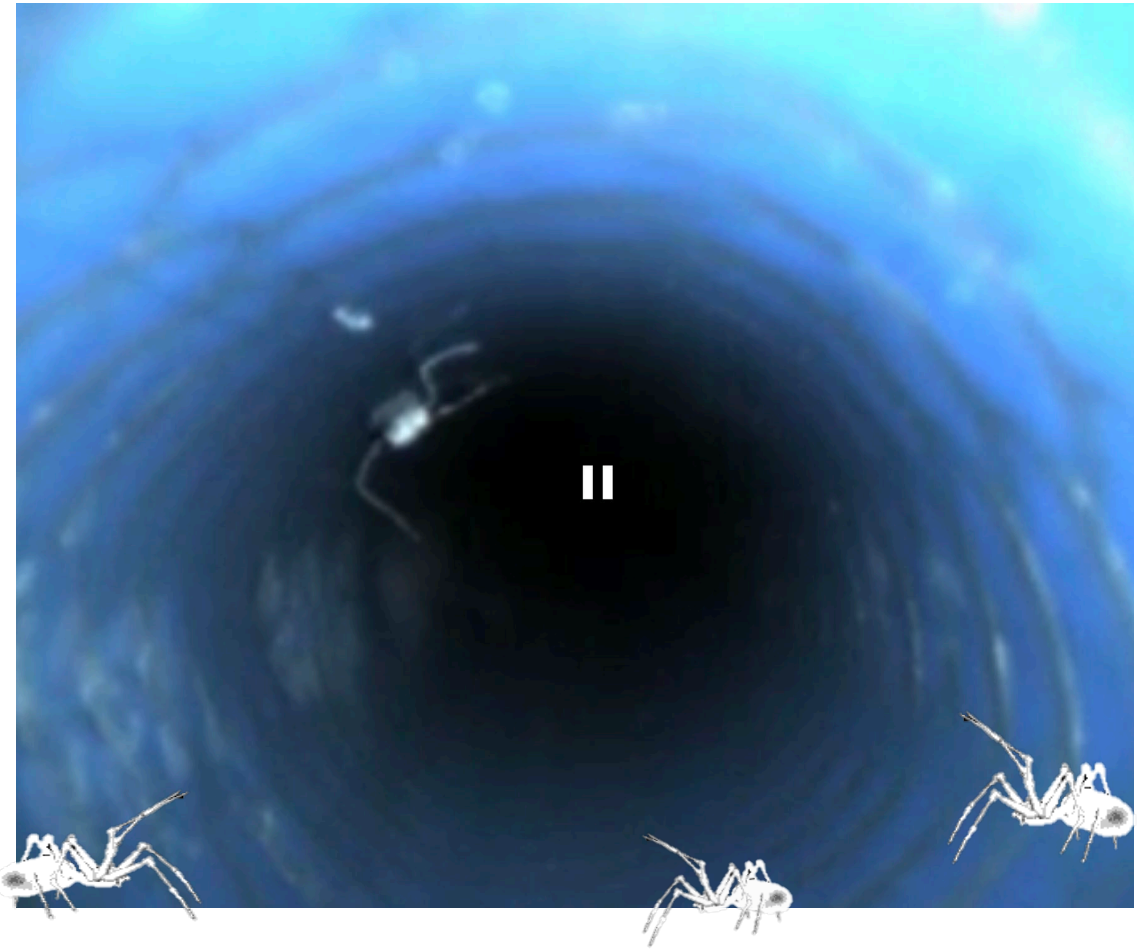
Borescope examination photos using a Flexible Inspection Scope (FIS)



Fluid in Channel of "DRY" scope



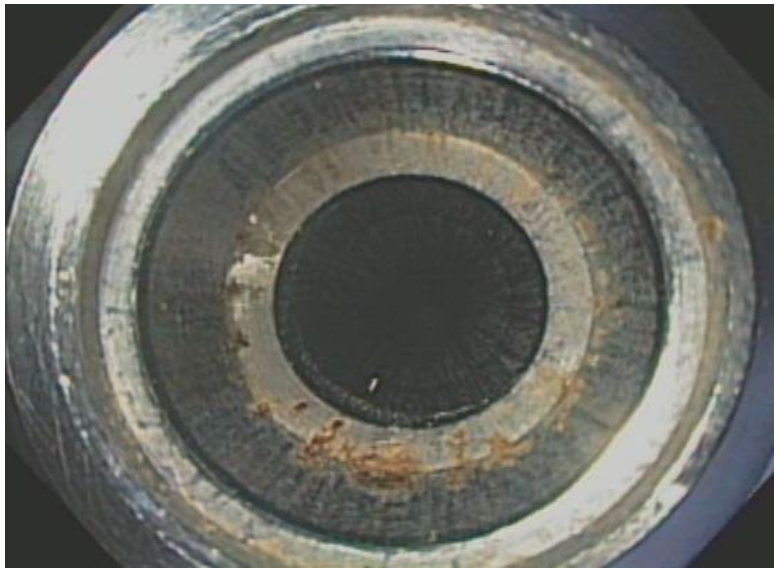
Debris inside a channel

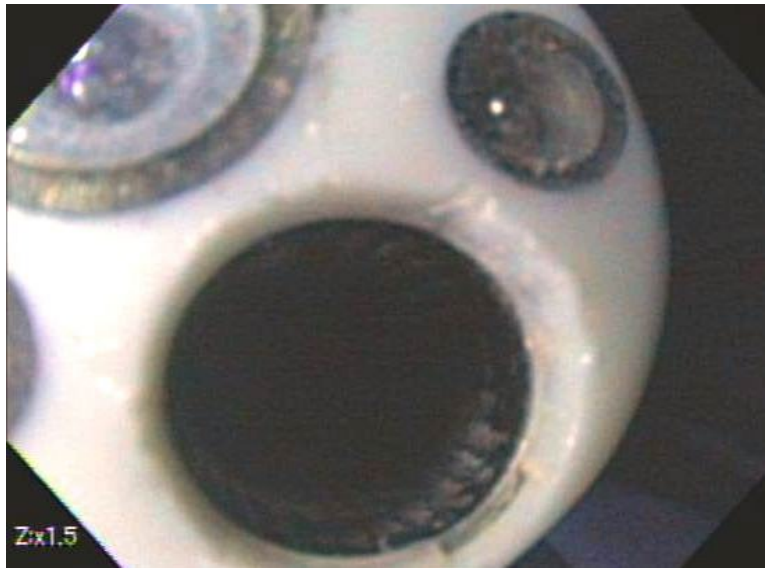


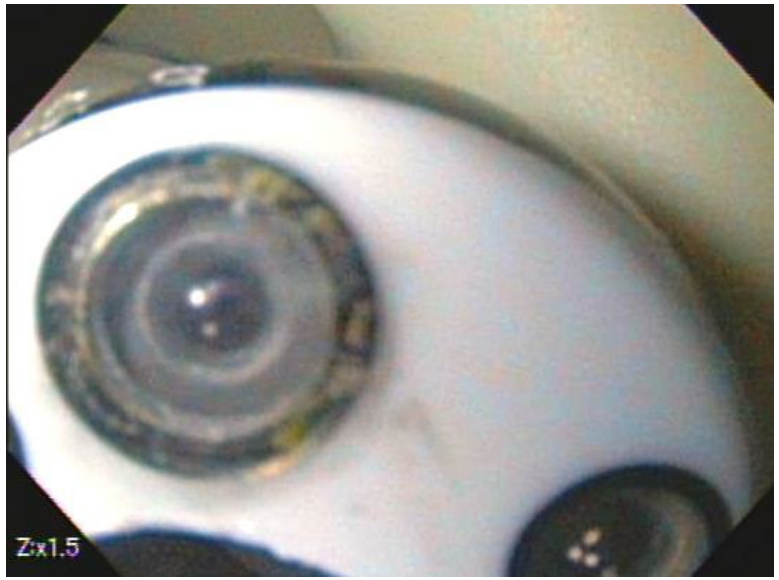
Don't forget to look for spiders!!

Borescope

Examples of Debris and Damage Found in Endoscopes



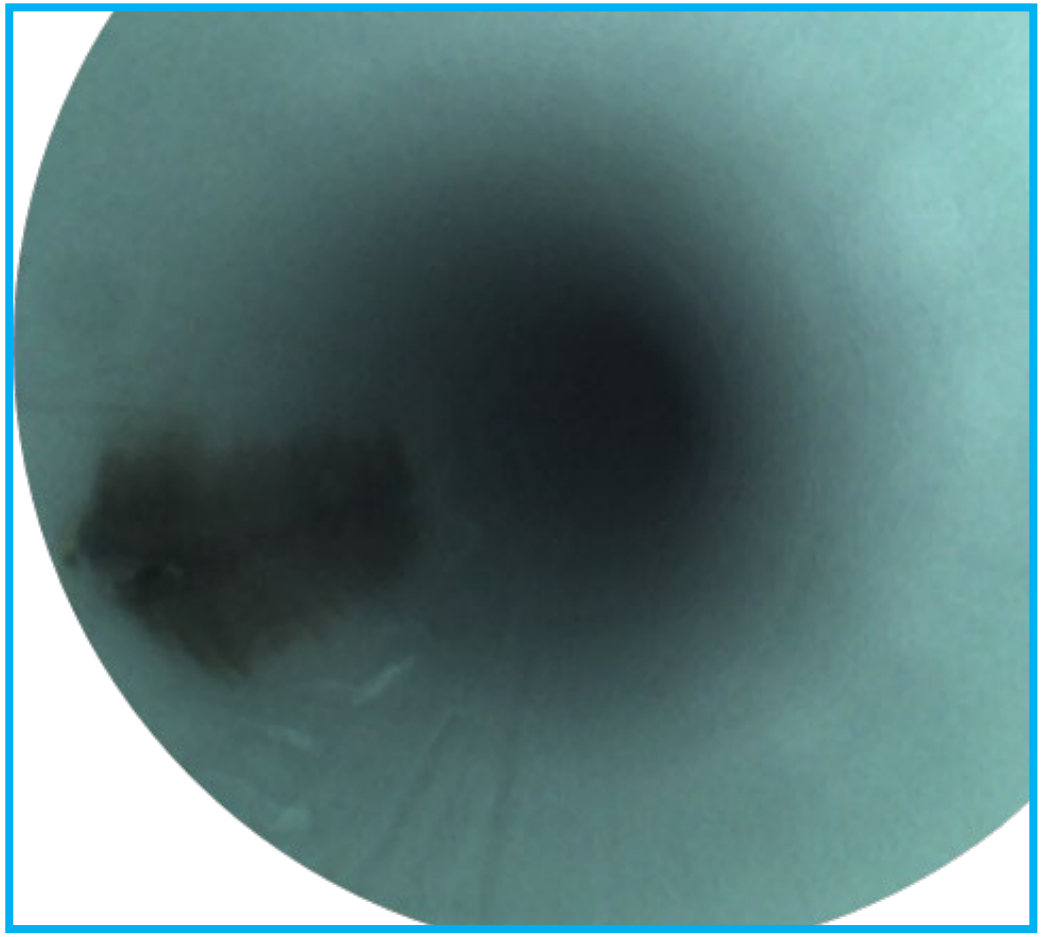




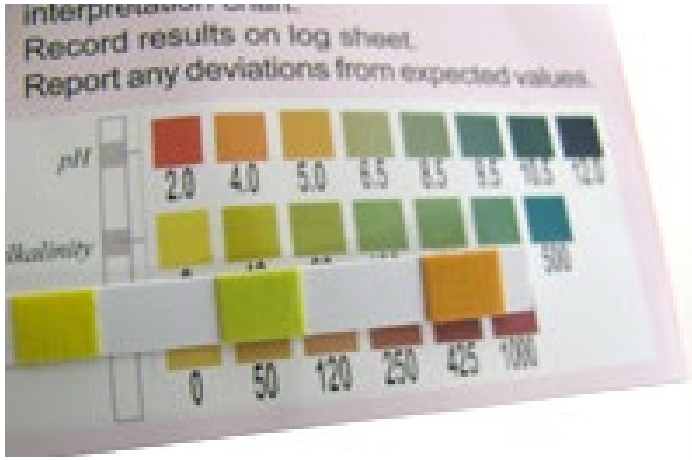
Two deaths reported 5/6/16

Olympus was informed that following ERCP procedures, six patients were infected with E. coli, and two of the six patients expired.

- A borescope was used to inspect the biopsy and suction channels.
- Brown stains and a scrape marks were found on the biopsy channel interior at 5 cm from the distal end.
- The suction channel had similar brown stains at various locations.



Water Monitoring & Cleaning Verification



Water Monitoring

Should:

- Periodic microbial assessment of AER to identify water contaminants

Cleaning Verification Testing

- High risk scopes- **SHALL** be monitored with cleaning verification after each use

- Scopes not high risk- **SHOULD** be verified using cleaning verification tests when new endoscopes are purchased and at established intervals (e.g. frequency based on number of procedures)
  -AAMI ST91 Annex G -Effects of simethicone on flexible endoscopes

Manual Cleaning Verification Monitors

Channel Sampling

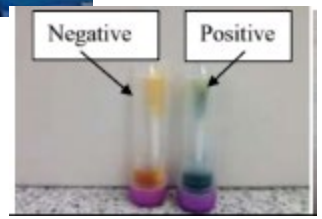
Flush methods

Combination test strips - carbohydrate, protein, and hemoglobin

Semi-quantitative protein test strip

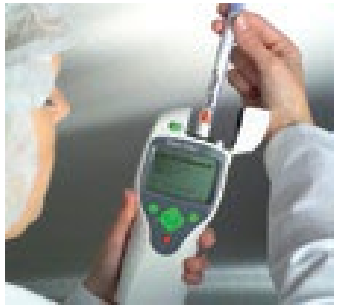
Swab methods

protein and hemoglobin



ATP Systems

Detects ATP via flush and swab methods – many systems available



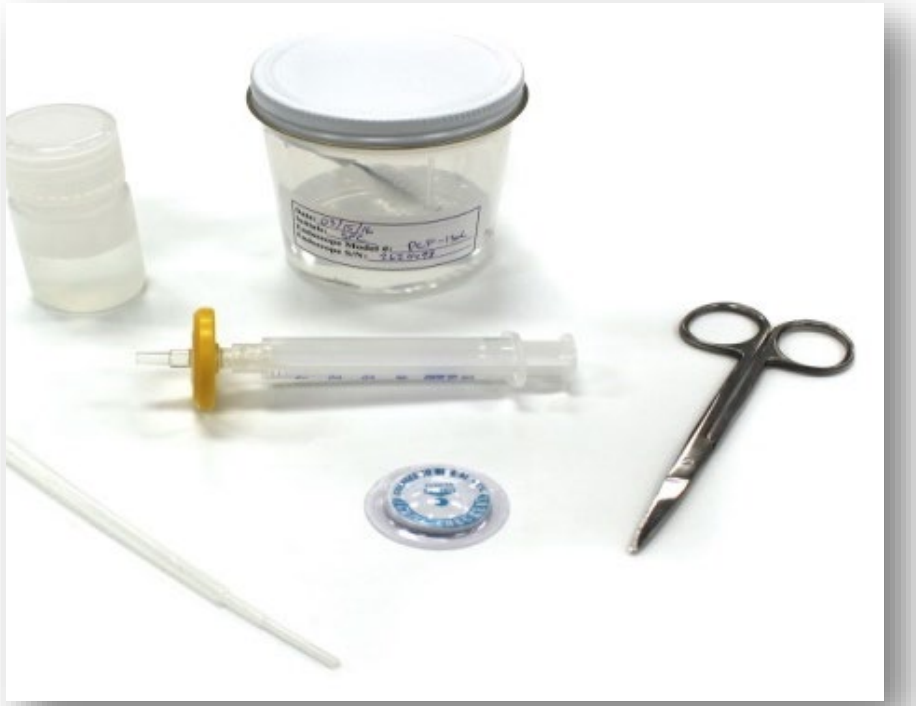
Microbial Surveillance

Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication - August 4, 2015

List of supplemental duodenoscope reprocessing measures

- Microbiological Culturing
- Ethylene Oxide Sterilization
- Use of a Liquid Chemical Sterilant Processing System
- ~~Repeat High-Level Disinfection~~

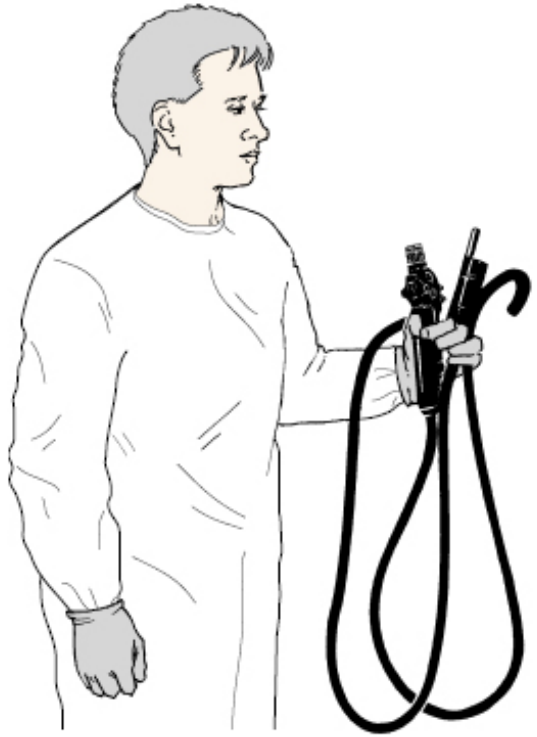
This option is no longer mentioned in the new FDA safety alert



- AAMI: Use of microbial testing as a quality assurance measure is advised
- AORN: Base decision on a risk assessment
- SGNA: Surveillance cultures can be used as a method for assessing reprocessing quality and aid in identifying particular endoscope defects that hamper effective reprocessing

AAMI ST91:2021 Section 13.6.3

Proper Handling and Gloves



AAMI ST91:2021 Section 6.3.4.1

"Education and training for endoscopes processing personnel should include proper endoscope handling."
(Pic shows proper way to hold scope)

AAMI ST91:2021 Section 11.2.3

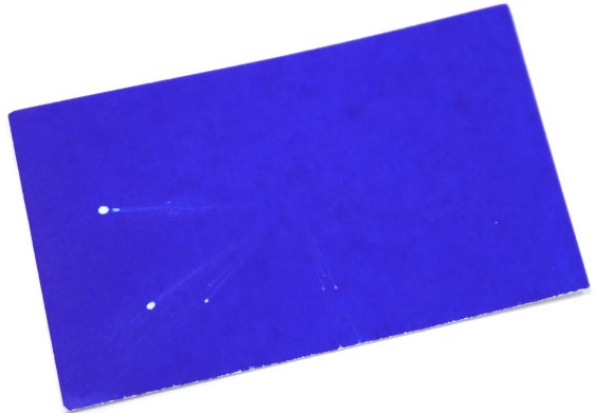
" The user should perform hand hygiene and don new, clean, non-latex gloves, according to the facility's policy, when handling processed endoscopes."

Drying

- Endoscopes should be dried after cleaning and disinfection process
  - -minimum 10 min with pressure-regulated forced instrument air or a minimum of HEPA-filtered air
  - -Never store wet
- Dry externally with unused, clean or sterile non-linting cloth
- Dry after AER cycle
  - -AER have air purge, not drying
- Alcohol flush-multi-disciplinary team
- Space requirements for drying

AAMI ST91:2021 Section 8.2.5

AAMI ST91:2021 Annex K



Storage of Processed Endoscopes

- Stored vertically or horizontally
- Storage cabinets minimum HEPA filter
- Cabinets cleaned weekly and logged
- Before placing in storage cabinet, label or tag should be attached
  -scotch tape not acceptable

AAMI ST91:2021 Section 11

Current recommendations for length of storage “hang time”

- AAMI ST91: Due to lack of consensus it is recommended to perform a **risk assessment** to establish maximum length of storage.
- AORN: Perform a **risk assessment** with a multi-disciplinary team to establish a policy for maximum storage time that processed flexible endoscopes are considered safe to use without reprocessing.
- SGNA: **7 days** based on a systematic review, if scopes are effectively reprocessed and stored in a way that keeps them completely dry and free from environmental and human contamination.

Design of Processing Area

Should be:

- Physically separated from patient care areas & procedure rooms
- Designed for processing only
- Allow for unidirectional flow of devices from receipt to storage
- Two separate rooms for processing endoscopes
  - -Until this can be achieved, strict unidirectional flow
  - -Minimum 4ft separation between decontam and clean work area with a wall or barrier extending 4ft above sink rim
- Adequate space for cleaning and rinsing
- Minimum of 2 bay sinks (3 preferred)

Test your leak testers!

- "Pressure verification should be performed for each type of leak tester in the facility each day that endoscopes are used."
- "Documentation of testing results should be recorded."
- Incorrect pressure output handicaps complete discovery of leaks – a common repair issue.
- (Olympus IFU wording) "Depress the pin located inside the connector cap of the leakage tester and confirm that air is emitted from the connector cap with a whoosh sound."
- Must check both the base unit and the hose
- Send leak tester for repair if not functioning properly.

AAMI ST91:2021 Section 7.4

Leak Test Observation Time

AAMI ST91:2021 Section 7.4.4

Observation for wet leak testing increased from 30sec to 60 sec.

Transport of Soiled Endoscopes

- Isolate and transport endoscope & components in a closed container or cart
  - -Unless controlled connected area
- Container or cart **MUST** be labeled with a visible biohazard & must meet OSHA requirements (29 CFR 1910.030) for transporting hazardous material
- The closed container or cart **MUST** be nonporous, leak proof, puncture resistant, and the correct size as to not damage the scope.
- Keep endoscopes moist but not submerged for transport
  - -Pretreatment solution, water-moistened towel, or humidity chamber bag

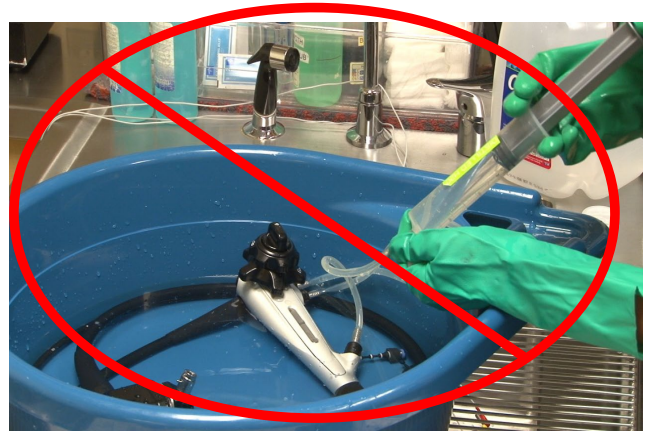
AAMI ST91:2021 Section 7.3 & 12

Use of container with an IFU
- -No bins from Walmart and Container store

Spaulding Classification

Patient Contact	Examples	Device Classification	Minimum Inactivation Level
Intact skin		Non-Critical	Cleaning and/or Low/Intermediate Level Disinfection
Mucous membranes or non-intact skin		Semi-Critical	Cleaning and **Sterilization** * If not possible, then High-Level Disinfection
Sterile areas of the body, including blood contact		Critical	Cleaning and Sterilization

Additional Guidance



- Manual disinfection no longer recommended!

AAMI ST91:2021 Section 8.2.4.1

- Effects of simethicone on flexible endoscopes

AAMI ST91:2021 Annex G

- More emphases in utilizing disposable valves.
  Unique concern= Option #1 – single-use caps and valves

AAMI ST91:2021 Section 10

- Certification within 2 years

AAMI ST91:2021 Section 6.3.1

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•Ofstead C.L., Wetzler H.P., Johnson E.A., et al.
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•Thaker A.M., Kim S., Sedarat A., et al.
Inspection of endoscope instrument channels after reprocessing using a prototype borescope.
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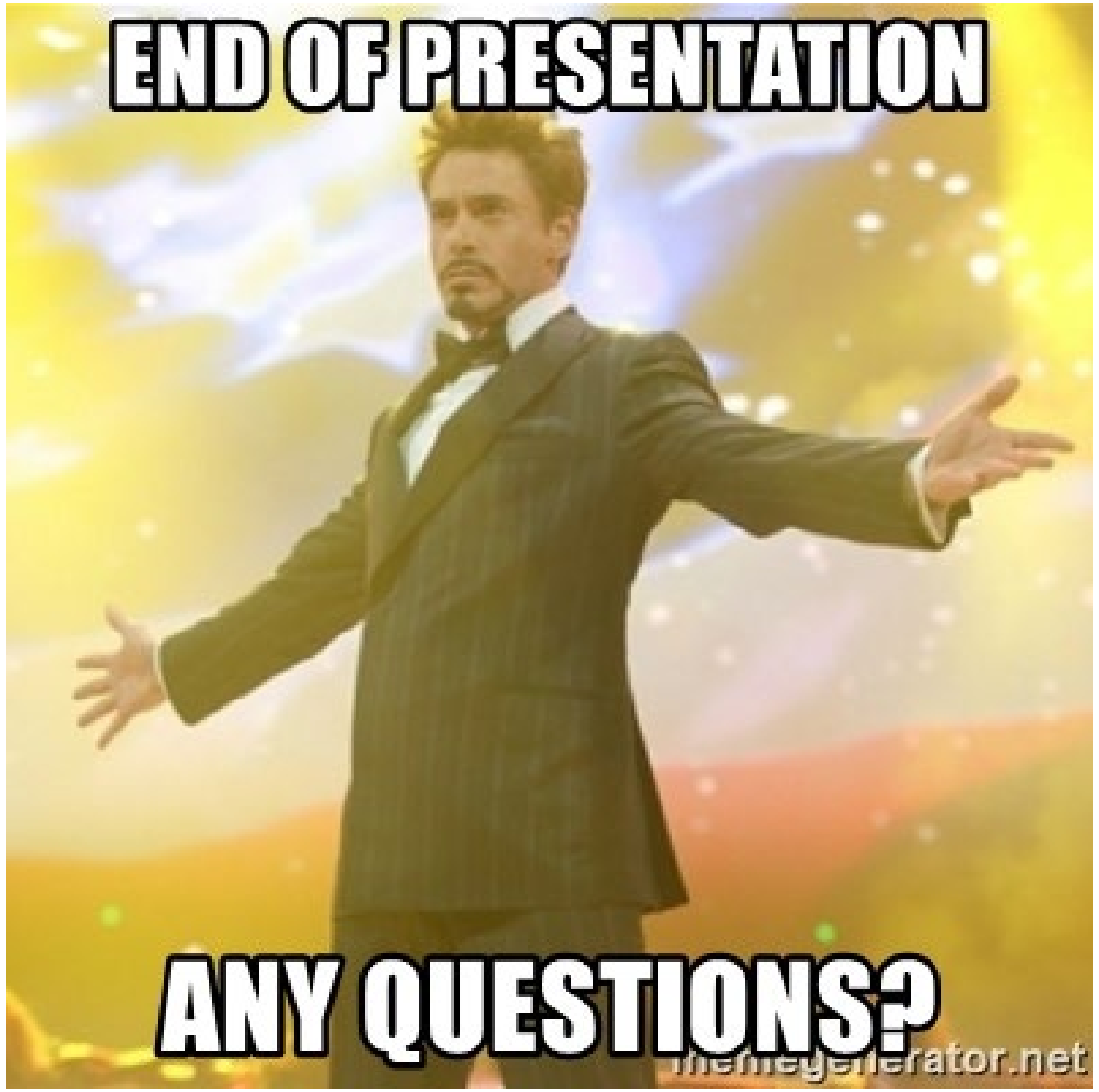
END OF PRESENTATION
ANY QUESTIONS?
memegenerator.net

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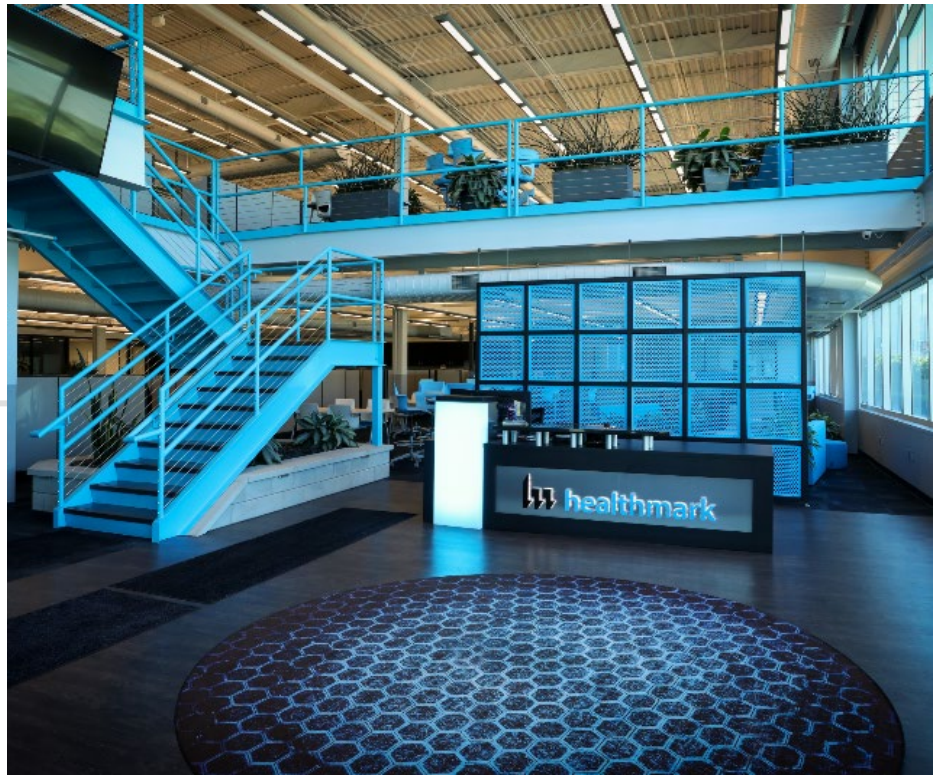

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