APIC Great Lakes: 2024 Educational Webinar Series

Hot Topics in Endoscope Reprocessing

May 21, 2024

Housekeeping

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Continuing Education (CE)

- CEs for today's session will be provided by Healthmark

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APIC Great Lakes Chapter Virtual Education Webinar

05-21-24

Hot Topics in Endoscope Processing

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Healthcare career - More than 45 years.

- 20+ years in Endoscopy.
- 4 years system role – overseeing HLD and endoscope processing for academic health system. Launch of the Centralized Endoscope Reprocessing Department on the main medical campus.
- 5 years Healthmark Educator

Memberships:

- APIC, AAMI, SGNA, ASGE, AORN.

Disclosures

- Presenter is 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).

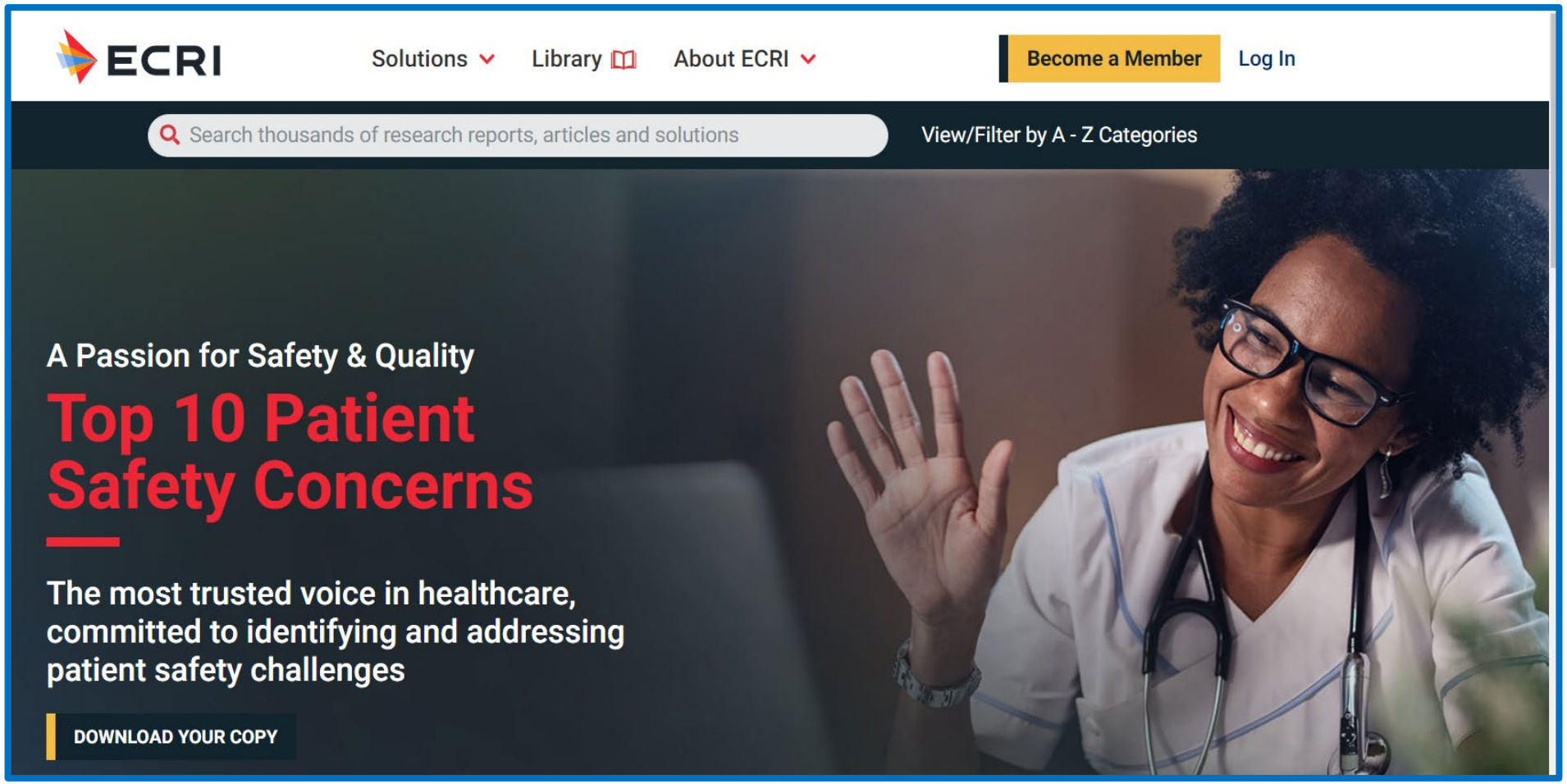
Healthmark Policy

Healthmark's Policy is to provide our customers and the healthcare community with the highest quality, state of the art medical products and support services in a timely and cost-effective manner.

This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence. This presentation is part of that commitment, educating our customers.

Objectives

- Update on most current guidelines for endoscope processing.
- Overview of latest hot topics in endoscope processing.
- Discuss the future of sterilizing endoscopes and other endoscope trends and technology.



https://www.ecri.org/

Significance and risk is not waning

ECRI Top Ten Lists - https://www.ecri.org

2018 –

#2 - Endoscope Reprocessing Failures Continue to Expose Patients to Infection Risk

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2019 –

#5 - Mishandling Flexible Endoscopes after Disinfection Can Lead to Patient Infections


ECRI

SPECIAL REPORT

Top 10 Patient Safety Concerns 2020

Executive Brief

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 looming patient safety challenges and offers suggestions and resources for addressing them.

The List for 2020

1. Missed and Delayed Diagnoses
2. Maternal Health across the Continuum
3. Early Recognition of Behavioral Health Needs
4. Responding to and Learning from Device Problems
5. Device Cleaning, Disinfection, and Sterilization
6. Standardizing Safety across the System
7. Patient Matching in the Electronic Health Record
8. Antimicrobial Stewardship
9. Overrides of Automated Dispensing Cabinets
10. Fragmentation across Care Settings

Top 10 Patient Safety Concerns 2020 | 1

ECRI Top Ten Lists - https://www.ecri.org

2018 –

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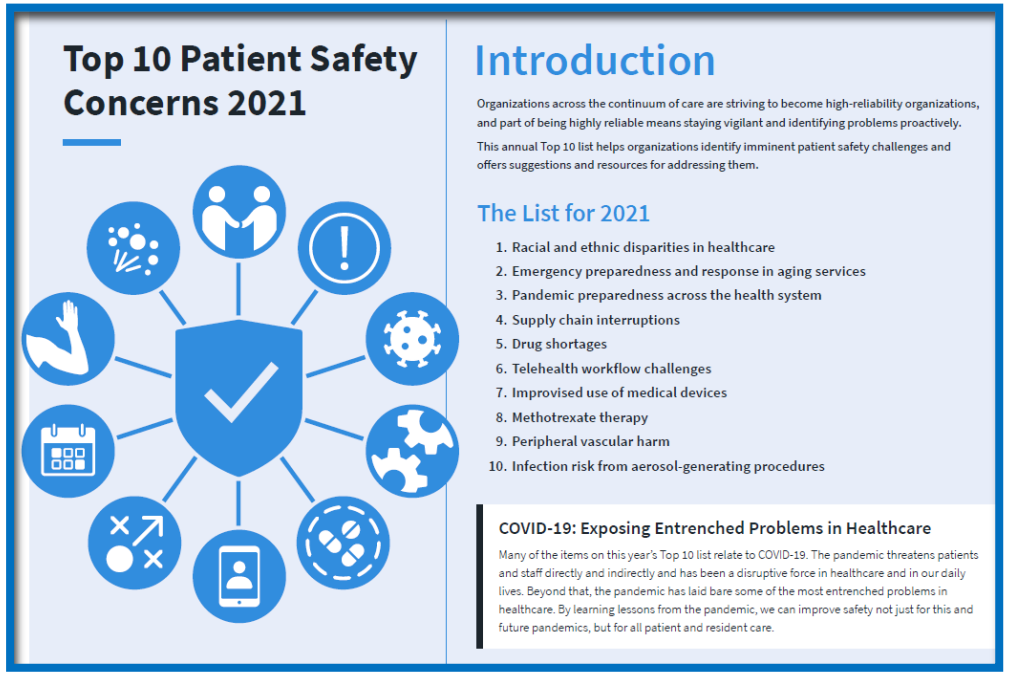
2020 –

#4 - Responding to and Learning from Device Problems

#5 - Device Cleaning, Disinfection, and Sterilization

#6 - Standardizing Safety across the System



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.

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

Poor Duodenoscope Reprocessing Ergonomics and Workflows Put Healthcare Workers and Patients at Risk

EIGHT

8

The failure to adequately reprocess contaminated duodenoscopes between uses is a well-known hazard, one that has led to the spread of deadly pathogens. Perhaps less well known are the risks of injury to the healthcare workers who perform this function, and the ways in which ergonomic and workflow factors can compromise reprocessing effectiveness, putting patients at risk.

A 2021 ECRI survey of healthcare workers who routinely perform duodenoscope reprocessing—that is, cleaning and disinfection (or sterilization)—identified several significant patient and worker safety hazards:

- Obstacles to effective reprocessing, potentially increasing patient infection risks. Survey respondents cited time pressures and poor work environment ergonomics (e.g., work surfaces at an uncomfortable height) as key concerns.
- The continued use of duodenoscopes with fixed distal endcaps, instead of scopes with single-use components. Duodenoscopes with fixed distal endcaps are more difficult to reprocess effectively, putting patients at increased risk of infection.
- A higher risk of healthcare worker musculoskeletal injuries due to poor workspace ergonomics

Correcting these problems requires facilities to take a close look at the workflow, the workspaces and surfaces, and the expected turnaround times for duodenoscope reprocessing, as well as reevaluating the use of reusable duodenoscopes.

> Ergonomic and workflow factors can compromise reprocessing effectiveness, putting patients at risk.

Top 10 Health Technology Hazards for 2022

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Self-Assessment: Establishing a Health Information Technology Safety Program (Health System Risk Management)

Self-Assessment: EHR Vendor Checklist (Health System Risk Management, Ambulatory Care Risk Management)

Detecting Changes in Patient Condition

Communication (Health System Risk Management, Aging Services Risk Management)

Documentation: A Primer on Charting in the Medical Record (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Nursing Liability (Health System Risk Management)

Clinical Alarms (Health System Risk Management)

Beat the Buzzer: The Alarm Safety Game Show! (Health System Risk Management)

Triage Toolkit (Ambulatory Care Risk Management)

Culture of Safety and the Infrastructure for Safety

Culture of Safety: An Overview (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Measuring Safety Culture (Health System Risk Management, Aging Services Risk Management, Ambulatory Care Risk Management)

Patient Safety and Quality Improvement Act (Health System Risk Management, Aging Services Risk Management)

Patient Safety, Risk, and Quality (Health System Risk Management)

The Role of the Patient Safety Officer (Health System Risk Management)

Culture of Safety 101 Training Program (Ambulatory Care Risk Management)

Device Cleaning, Disinfection, and Sterilization

ECRI's Infection Prevention and Control Services

Reprocessing of Reusable Medical Devices (Health System Risk Management)

Reprocessing of Flexible Endoscopes (Health System Risk Management)

Overview of Infection Prevention and Control (Health System Risk Management, Aging Services Risk Management)

Infection Prevention and Control (Ambulatory Care Risk Management)

Self-Assessment: Instrument Sterilization and Disinfection Practices (Health System Risk Management)

Environmental Infection Control Toolkit (Ambulatory Care Risk Management)

Care Fragmentation and Poor Care Coordination

Deep Dive: Care Coordination (ECRI and the ISMP PSO)

Inpatient Care Coordination (Health System Risk Management)

Discharge Planning (Health System Risk Management)

Transitions of Care (Aging Services Risk Management)

Subacute Care (Aging Services Risk Management)

Care Coordination and Transitions (Ambulatory Care Risk Management)

Guidance for Patient Safety Toolkit: Handoff Communication (ECRI and the ISMP PSO)

Antimicrobial Stewardship

Physician Leader Huddle: Antimicrobial Stewardship (ECRI and the ISMP PSO)

Overview of Infection Prevention and Control (Health System Risk Management, Aging Services Risk Management)

Infection Prevention and Control (Ambulatory Care Risk Management)

Patient Identification

Deep Dive: Patient Identification (ECRI and the ISMP PSO)

Patient Identification: Implementation Guide and Toolkit (Partnership for Health IT Patient Safety)

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Recurrent Patient Safety Challenges

Over the years, the following patient safety concerns have made repeat appearances on ECRI's list of Top 10 Patient Safety Concerns; the list begins with the most frequently mentioned:

- Medication safety
- Diagnostic stewardship and test result management
- Behavioral health
- Health IT
- Detecting changes in patient condition
- Workforce staffing, skills, and safety
- Culture of safety and the infrastructure for safety
- Device cleaning, disinfection, and sterilization
- Medical devices and supplies
- Telehealth and digital health
- Care fragmentation and poor care coordination
- Antimicrobial stewardship
- Emergency preparedness
- Infection prevention and control
- Health equity
- Patient identification

For links to key ECRI and ISMP resources for each of these topics, members can log in at ecri.org. For information on ECRI and ISMP memberships, contact client services at (610) 825-6000, ext. 5891, or clientservices@ecri.org.

2023

- Culture of safety and the infrastructure for safety
- Device cleaning, disinfection, and sterilization
- Medical devices and supplies
- Infection prevention and control

2024 – ECRI Top Ten Heath Technology Hazards

- #2 - Inadequate or Onerous Device Cleaning Instructions Endanger Patients

  - "Successful reprocessing is made more challenging, however, by the wide variation in the content, quality, and feasibility of reprocessing instructions…"

  - "…incomplete, impractical, or onerous reprocessing instructions…"

  - "…reprocessing considerations should be evaluated during the pre-purchase risk assessment of a product."

Top 10 Health Technology Hazards for 2024

Executive Brief

ECRI is providing this Executive Brief describing its 2024 Top 10 list of health technology hazards to inform the healthcare community about key safety issues involving the use of medical devices and systems.

The List for 2024

1. Medical Devices May Pose Usability Challenges for Home Users, Risking Misuse and Patient Harm
2. Inadequate or Onerous Device Cleaning Instructions Endanger Patients
3. Sterile Drug Compounding without the Use of Technological Safeguards Increases the Risk of Medication Errors
4. Overlooked Environmental Impacts of Patient Care Endanger Public Health
5. Insufficient Governance of AI Used in Medical Technologies Risks Inappropriate Care Decisions
6. Ransomware Targeting the Healthcare Sector Remains a Critical Threat
7. Increased Burn Risk with Single-Foil Electrosurgical Return Electrodes
8. Infusion Pump Damage Remains a Medication Safety Concern
9. Poor QC of Implantable Orthopedic Products Can Lead to Surgical Delays and Patient Harm
10. Third-Party Web Analytics Software Can Compromise Patient Confidentiality

ECRI MEMBERS: LOG IN TO ACCESS THE FULL REPORT

Detailed descriptions of the hazards outlined in this Executive Brief, along with ECRI's step-by-step recommendations for addressing them, are provided in the 2024 Top 10 Health Technology Hazards Solutions Kit. Members of ECRI programs can access the Solutions Kit through their membership web pages. For more information, contact clientservices@ecri.org; call +1 (610) 825-6000, ext. 5891; or visit www.ecri.org.

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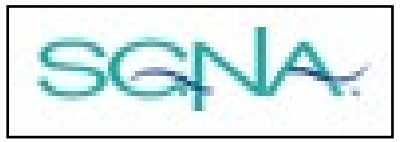
Regulations/Standards/Guidelines – U.S.

- Regulations
  - A rule or directive made and maintained by an authority
  - Mandatory
- Standards
  - Requirements and specifications to ensure consistency and fit for purpose
  - Voluntary, but can become mandatory
- Guidelines, Recommended Practices, Technical Information reports
  - Technical guidance, information or preferred procedures regarding a given topic
  - Voluntary but with interpretation



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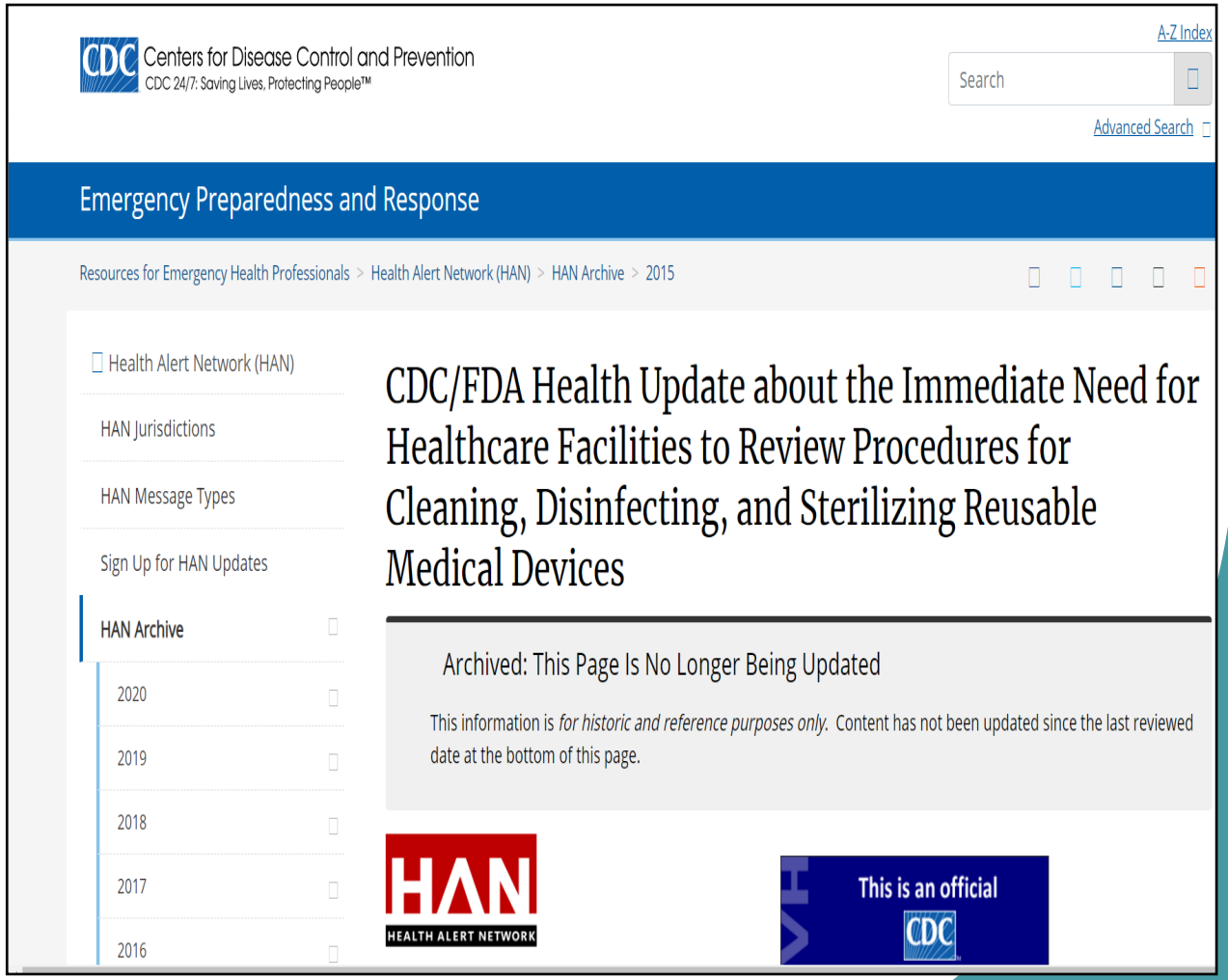
This is, and has been, a dynamic process – stay connected and up-to-date



Safety Communications

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The FDA posts Medical Device Safety Communications to describe the 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. Older safety communications are denoted by (Archive).

Content current as of:
02/21/2024

Regulated Product(s)
Medical Devices
Radiation-Emitting Products

Safety Communications

- 2024 Safety Communications
- 2023 Safety Communications
- 2022 Safety Communications
- 2021 Safety Communications (Archived)
- 2020 Safety Communications (Archived)
- 2019 Safety Communications (Archived)
- 2018 Safety Communications (Archived)
- 2017 Safety Communications (Archived)
- 2016 Safety Communications (Archived)
- 2015 Safety Communications (Archived)
- 2014 Safety Communications (Archived)
- 2013 Safety Communications (Archived)
- 2012 Safety Communications (Archived)
- 2011 Safety Communications (Archived)
- Safety Communications Issued Prior to 2011 (Archived)

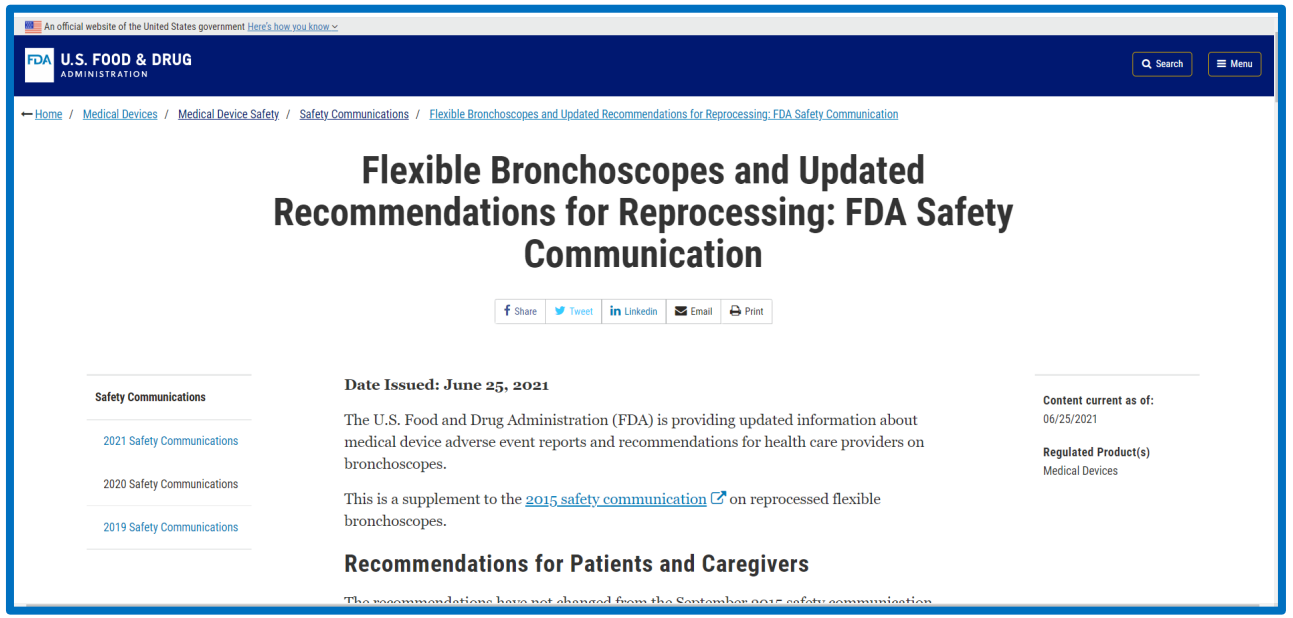
Additional Resources

- Report to Congress: Postmarket Device Safety-Related Communications

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

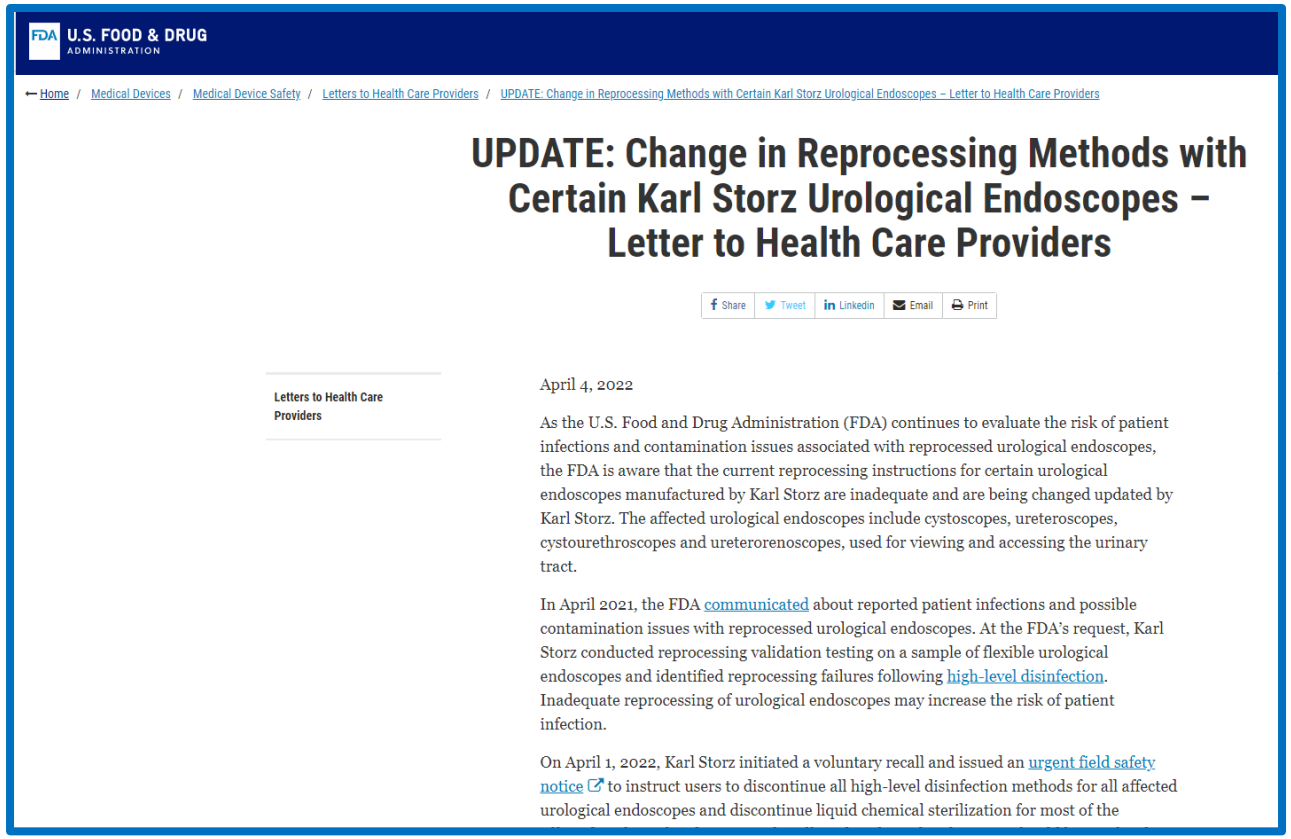
06-25-21 - supplement to their 2015 safety communication re: flexible bronchoscopes.

- Reminder – carefully follow manufacturers' IFUs.
- Consider sterilization instead of HLD.
- Do not use damaged devices, or those failing leak tests.
- Routine inspection and maintenance.
- Consider single-use bronchoscopes where there is increased risk.
- Updated information on related MAUDE reports.



04-04-22 – significant reprocessing instruction change.

- FDA notice re: patient infections and possible contamination issues with urological scopes.
- Reprocessing failures identified after FDA requested validation testing.
- Voluntary recall by manufacturer with urgent field safety notice – discontinue HLD and LCS – sterilize instead.



FDA U.S. FOOD & DRUG ADMINISTRATION

← Home / Medical Devices / Medical Device Safety / Letters to Health Care Providers / UPDATE: Change in Reprocessing Methods with Certain Karl Storz Urological Endoscopes – Letter to Health Care Providers

UPDATE: Change in Reprocessing Methods with Certain Karl Storz Urological Endoscopes – Letter to Health Care Providers

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Letters to Health Care Providers

April 4, 2022

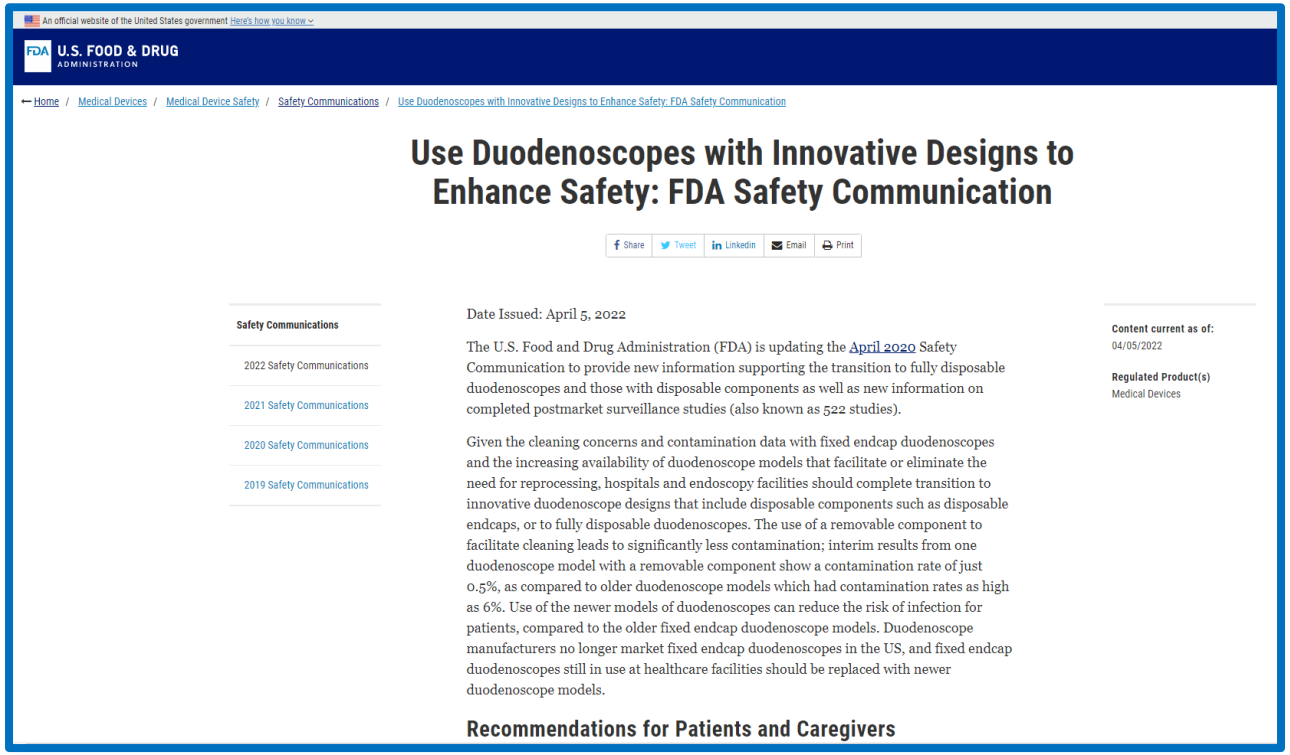
As the U.S. Food and Drug Administration (FDA) continues to evaluate the risk of patient infections and contamination issues associated with reprocessed urological endoscopes, the FDA is aware that the current reprocessing instructions for certain urological endoscopes manufactured by Karl Storz are inadequate and are being changed updated by Karl Storz. The affected urological endoscopes include cystoscopes, ureteroscopes, cystourethroscopes and ureterorenoscopes, used for viewing and accessing the urinary tract.

In April 2021, the FDA communicated about reported patient infections and possible contamination issues with reprocessed urological endoscopes. At the FDA's request, Karl Storz conducted reprocessing validation testing on a sample of flexible urological endoscopes and identified reprocessing failures following high-level disinfection. Inadequate reprocessing of urological endoscopes may increase the risk of patient infection.

On April 1, 2022, Karl Storz initiated a voluntary recall and issued an urgent field safety notice to instruct users to discontinue all high-level disinfection methods for all affected urological endoscopes and discontinue liquid chemical sterilization for most of the

04-05-22 – update to 04/2020 Safety Communication.

- Provides new information to support transition to fully/partially disposable duodenoscopes.
- Provides new information re: completed postmarket surveillance studies.
- HCF should complete transition to newer duodenoscopes.
- Contamination rates:
  - Older models – as high as 6%.
  - One newer model with disposable components – 0.5%



FDA recommendations

- Follow manufacturer’s IFUs.
- Adhere to professional reprocessing guidelines.
- Have a comprehensive QC program.
- Required documentation:
    - Training
    - Competencies
    - Quality monitors

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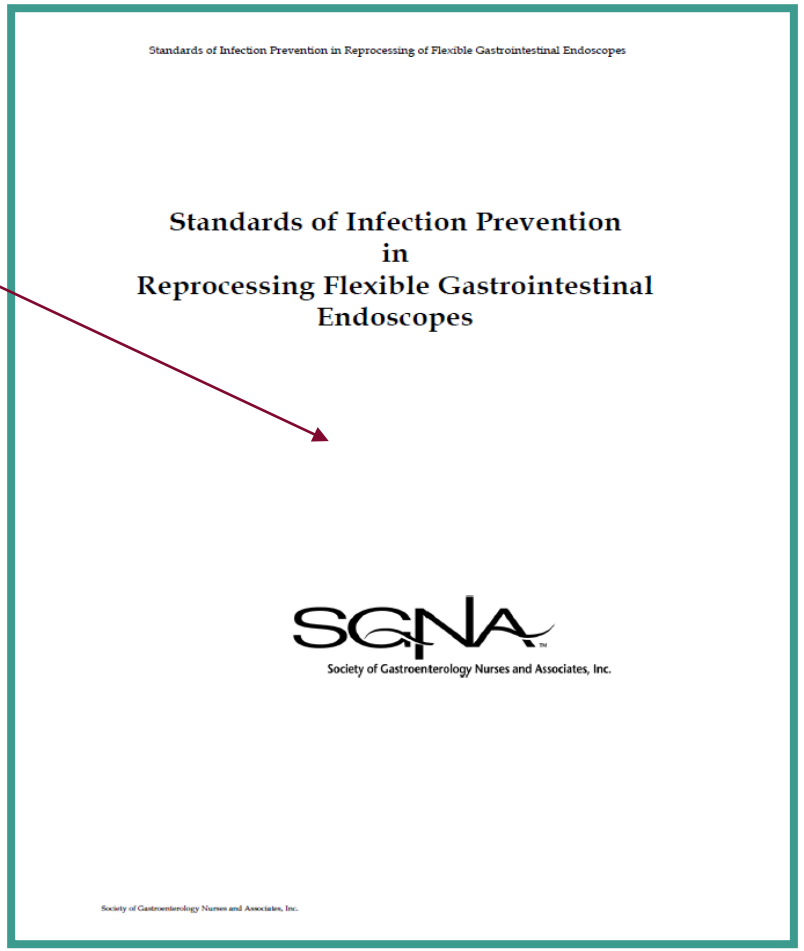
Organization	SGNA - Society of Gastroenterology Nurses and Associates	AORN - Association of periOperative Registered Nurses	AAMI - Association for the Advancement of Medical Instrumentation	ASGE - American Society for Gastrointestinal Endoscopy
Most recent year of publication	2023	2022	2022	2021
Standard/Guideline Title	Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes	Guidelines for Perioperative Practice: Flexible Endoscopes	ANSI/AAMI ST91: 2021 Flexible and semi-rigid endoscope processing in health care facilities	Multisociety guideline on reprocessing flexible GI endoscopes and accessories
Replaces previous publication year	2018	2019	2015	2016

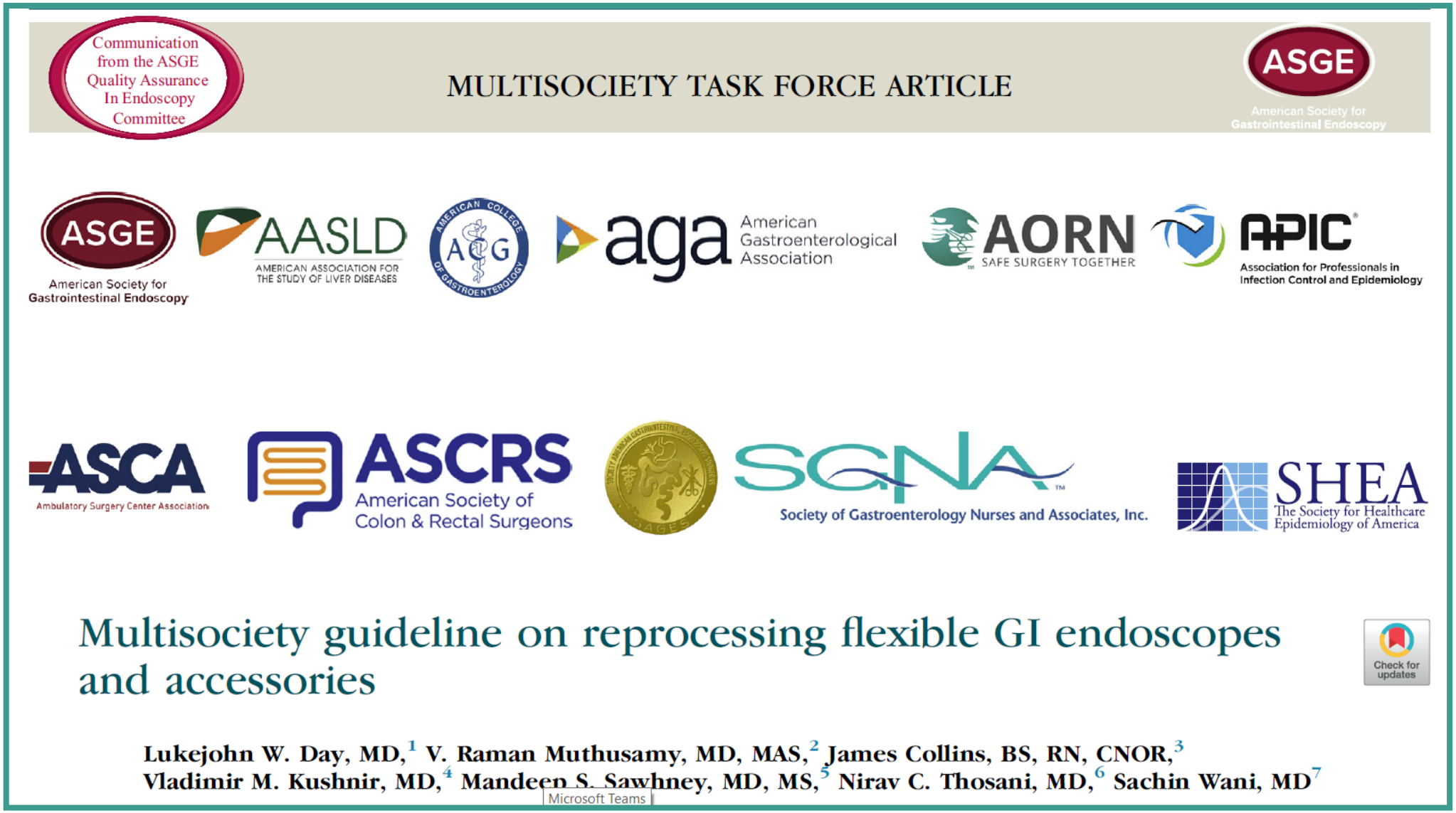
SGNA Standards and Practice Guidelines

- Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes (2023)
- Standard of Infection Prevention in the Gastroenterology Setting (2019)
- Management of Endoscopic Accessories, Valves, and Water and Irrigation Bottles in the Gastroenterology Setting (2018)
- Guidelines for the Use of High-Level Disinfectants & Sterilants in the Gastroenterology Setting (2017)



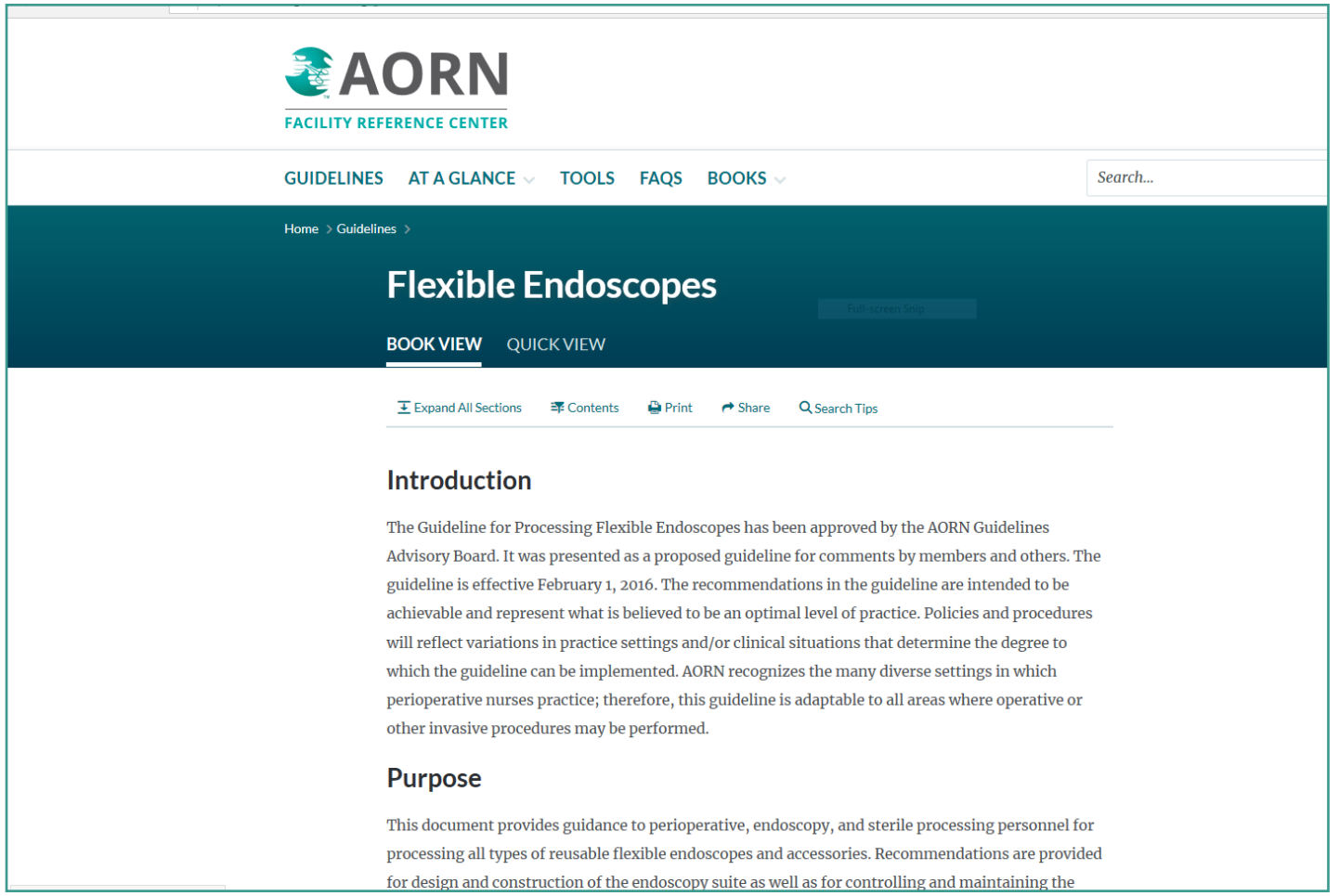
https://www.sgna.org/Practice/Standards-Practice-Guidelines

ASGE – Multisociety Guidelines - https://www.giejournal.org/article/S0016-5107(20)34851-3/fulltext



January 2021

AORN – Guideline for Processing Flexible Endoscopes



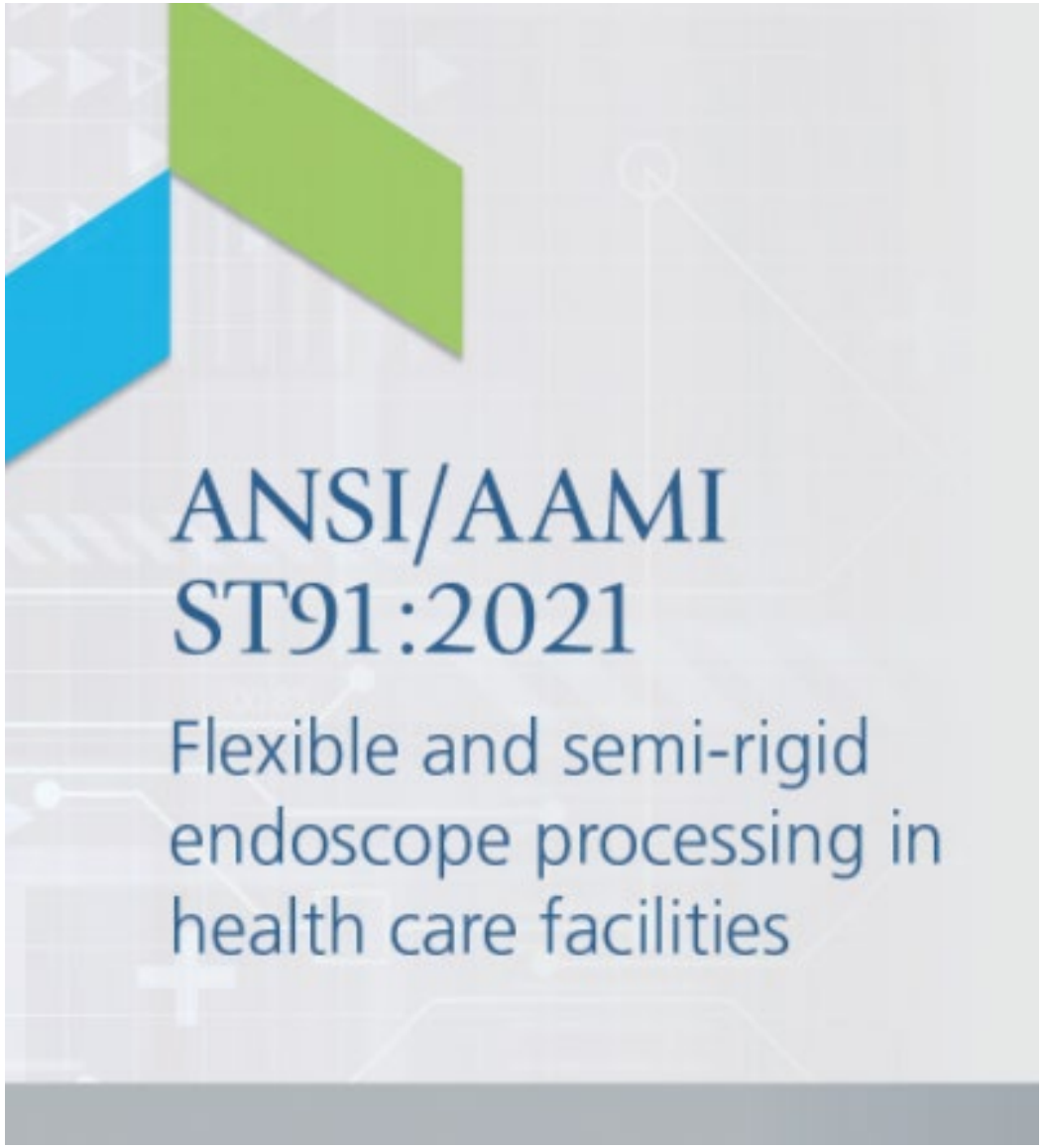
2022

ANSI/AAMI ST91: 2021 – Released 3/3/22

- Contains best practices for endoscope reprocessing in ANY setting
- Excludes TEE/ultrasound probes
- Coincidental work - **TIR 99:** processing of US probes & dilators

Focused changes to ST91 –

next presentation



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Replaces previous publication year	2018	2019	2015	2016

Institutional policies

ASGE

- "Endoscopy unit has a written environmental disinfection and endoscope reprocessing policy and staff are oriented to it."

AAMI

- "The health care facility should establish a multidisciplinary , comprehensive, written quality assurance and safety program for all aspects of endoscope processing."

AORN

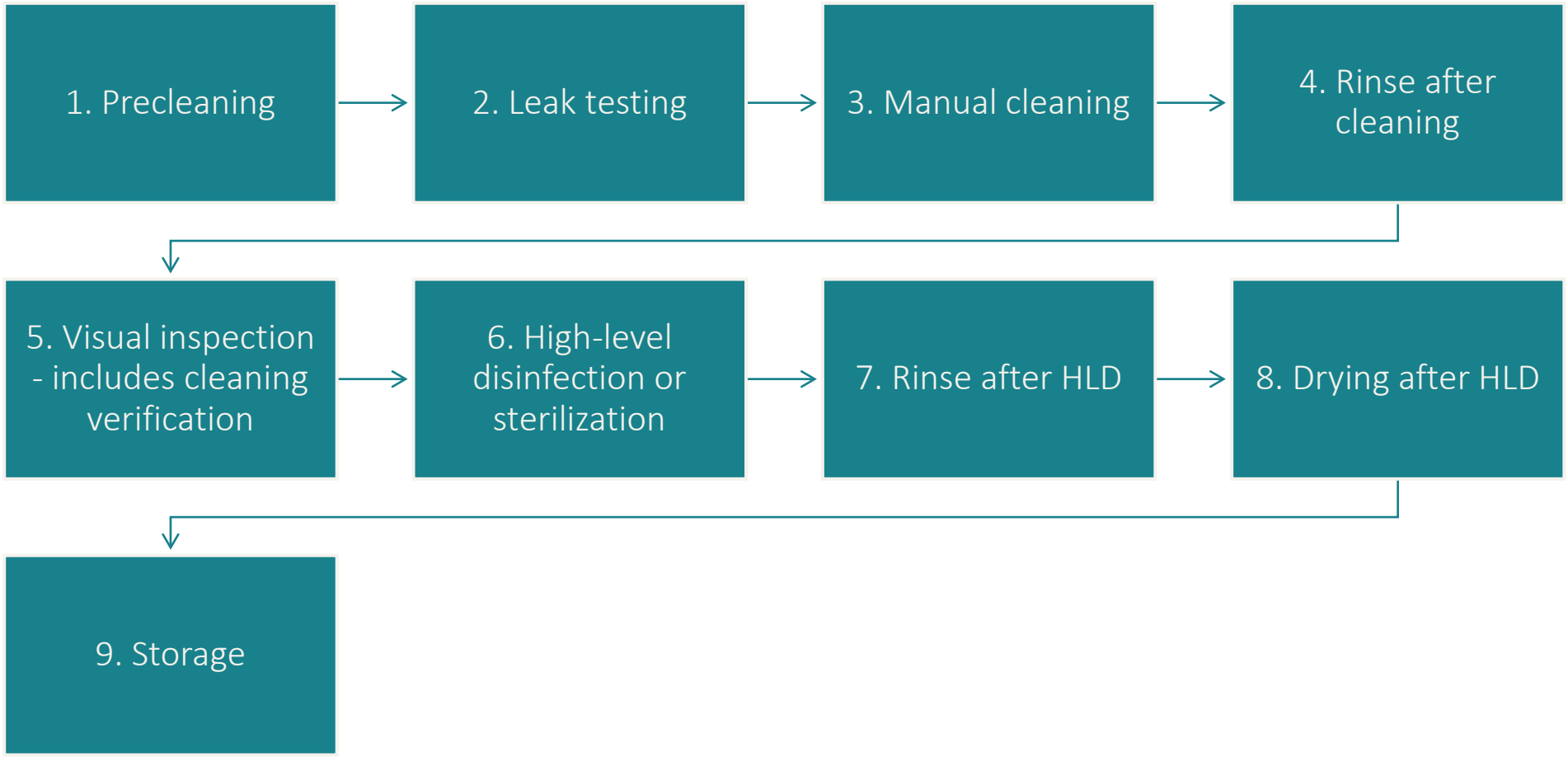
- "The healthcare organization must develop policies and procedures for processing flexible endoscopes, review them periodically, revise them as necessary, and make them readily available in the practice setting in which they are used."

SGNA

- "Best practices recommend…develop policies and procedures that focus on endoscope reprocessing."

Flexible Endoscope Reprocessing Steps

(adapted from Society of Gastroenterology Nurses and Associates)



REPROCESSING STEP: Point of use Treatment / Precleaning / Handoff

- Follow IFU

- Keep scopes moist for transport.

- Processing personnel need to know how long the endoscope has been awaiting processing
  - To establish priority order.
  - To determine whether routine processing within the manufacturer's recommended time to cleaning is achievable.
  - If not, requires implementing the manufacturer's procedures for delayed processing.

- Communicate procedure end time/precleaning start time
  - Need a method for conveying that time to reprocessing staff
  - AAMI ST91 (2021): "Handoff communication from point of use to the decontamination area shall include at minimum – patient identifier, date of procedure, and time point of use treatment was completed."

Soiled Transport

- Containment – commonly solid, leakproof, puncture resistant containers or transport carts
- Prevent cross contamination and damage to device
- Appropriate size transport container
- Labeling as contaminated (biohazard), NOT patient ready
- In U.S., needs to meet OSHA hazardous transport guidelines
- For offsite transport in U.S., needs to meet D.O.T., state, local regulations.

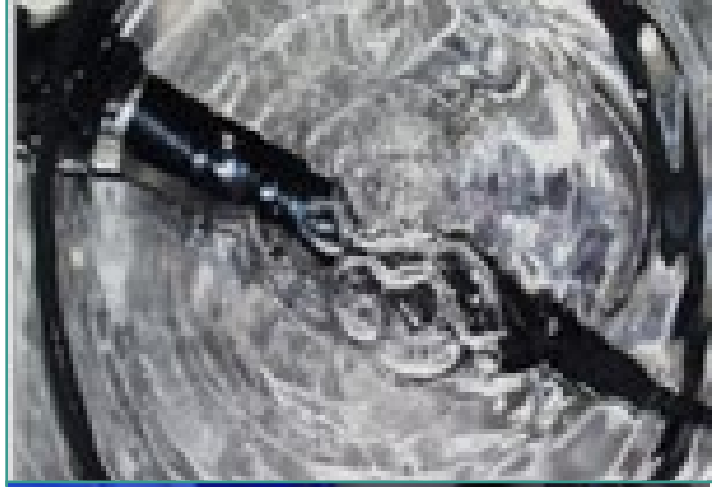
Delayed Reprocessing (Olympus)

- 1 hour hold time between precleaning & manual cleaning, and between manual cleaning & high-level disinfection
- IFU: Soak up to 1 hour for surgical scopes & up to 10 hours for GI scopes
- Customer statement 2018 - https://medical.olympusamerica.com/sites/default/files/us/files/pdf/Performing-a-Presoak-When-Endoscope-Reprocessing-is-Delayed.pdf
- Reprocessing Manuals: “Presoak for Excessive Bleeding and/or Delayed Reprocessing”

REPROCESSING STEP: Leak testing

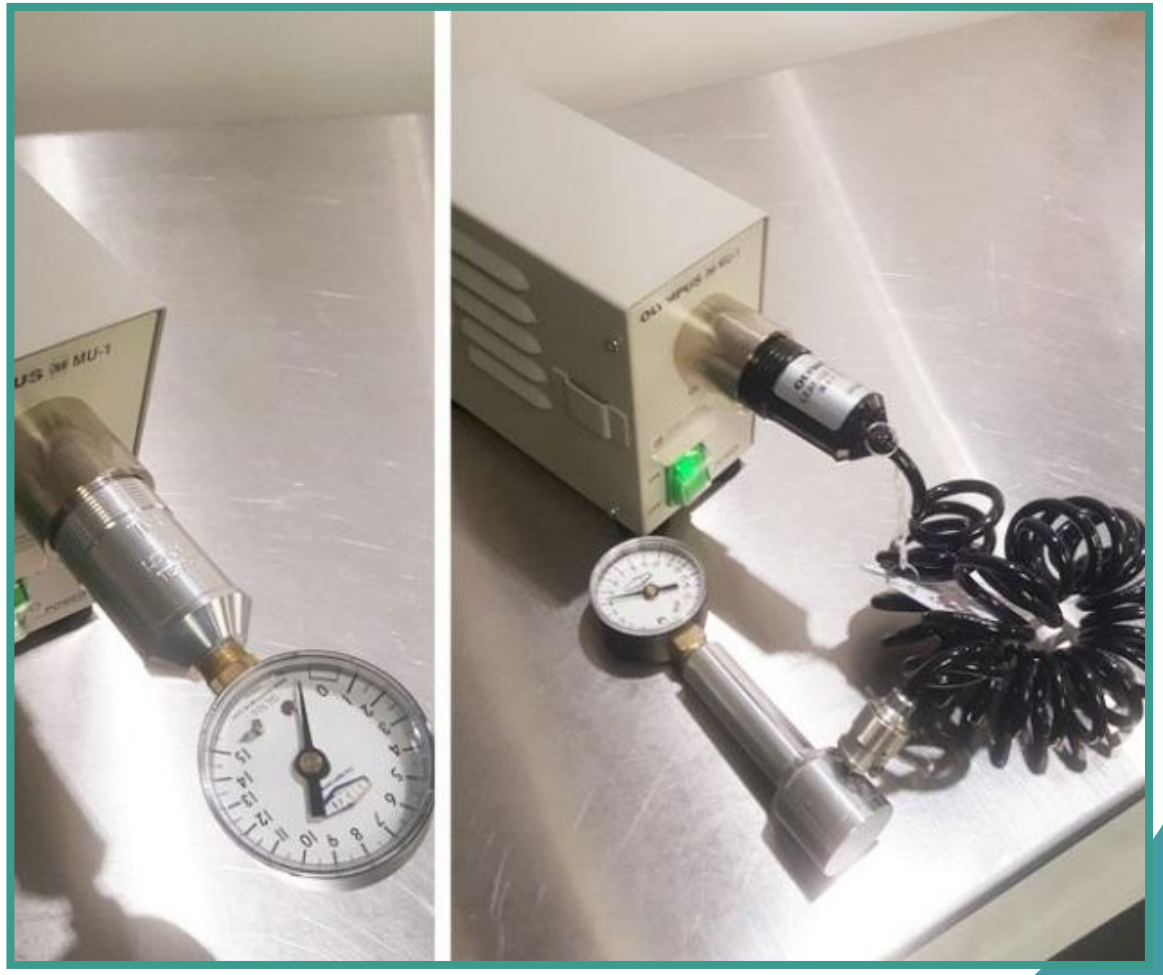
Common Errors

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



REPROCESSING STEP: Leak testing – QC for leak testers

- Faulty leak testers are both a device and an infection risk.
- 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."
- Part of a facility's quality management program to verify their equipment.
- AAMI ST91 (2021): "Automated leak testers should be placed on a calibration schedule to verify the leak tester is producing the correct pressure. Manual handheld leak testers and leak tester tubing should be inspected for damage, leakage, and pressure output".



REPROCESSING STEP: Manual cleaning - BRUSHING

- **AAMI ST91 (2021):** "Use brushes of the length, width, and material specified by the endoscope manufacturer's written IFU".
- **SGNA:** "Use a brush size compatible with each channel, bristles should contact all surfaces."
- **AORN:** "compatible brush in accordance with the manufacturer's IFU".
- **Multisociety Guideline:** "Use brushes appropriate for the size of the endoscope channel, parts, connectors, and orifices (e.g., bristles should contact all surfaces) for cleaning."

What About Automated Cleaning in an AER?

Some have FDA cleared cleaning claims.

- AAMI ST91 (2021):
  - If considering replacing full manual cleaning with automated cleaning, “convene a multi-disciplinary team to conduct a risk assessment”.
  - When it comes to duodenoscopes, the FDA recommendations are reinforced - that AER cleaning cycles only be a supplement to thorough manual cleaning.

- SGNA:
  - “…users are strongly encouraged to perform both (manual cleaning and brushing) even when automated washing of endoscope channels is used. The redundancy achieved by adding an automated washing step following manual cleaning can provide an extra level of safety.”

REPROCESSING STEP: Inspection

Standards & Guidelines -

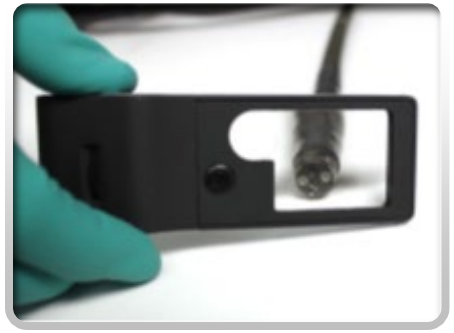
- AAMI
- AORN
- SGNA
- Multisociety Guideline

All support the practice of using lighted magnification for inspection.

Cleaning verification

- Research and investigations have highlighted the limitations of manual cleaning.
- Soil/biofilm that remains after cleaning may interfere with the disinfection or sterilization process.
- Cleaning verification as a part of focused inspection.
- Cleaning verification tests serve as a marker to show that the steps for processing followed resulted in an adequately cleaned endoscope.

	CLEANING VERIFICATION
AAMI	“High-risk endoscopes …shall be evaluated with cleaning verification tests after each use”.
SGNA	"Facilities should consider a method of manual cleaning verification."
AORN	"Manual cleaning of flexible endoscopes should be verified using cleaning verification tests when new endoscopes are purchased and at established intervals".

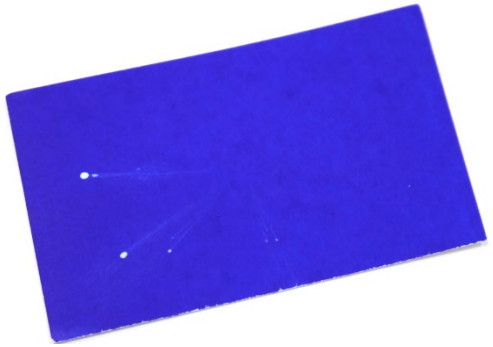


Enhanced visual inspection and cleaning verification –

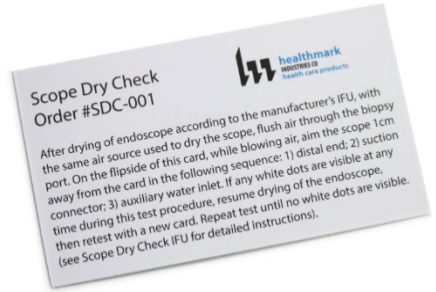
best practice and quality control that helps you evaluate what the naked eye cannot

Reprocessing step - Drying

- Scopes must be completely dry before going into storage or used clinically.
- Follow manual or AER cycle with **instrument quality** air drying.
  - (AER cycles are an air purge only)
- How do you know its dry? - Inspect with borescope or use a drying test



- AORN: "Drying should be completed outside of the AER, even when the AER has an air purge or extended dry time feature."
- SGNA: "Drying the endoscope after every reprocessing cycle, both between patient procedures and before storage, is crucial."
- AAMI ST91 (2021): Channeled endoscopes dried for a minimum of 10-minutes with pressure-regulated forced instrument air or a minimum of HEPA-filtered air.
- Multisociety Guideline: "Endoscopes should be completely dried after reprocessing and before use".



Reprocessing Step - Storage

- AORN and AAMI ST91 (2021): Drying cabinet preferred. If not, then cabinet with HEPA filtered air.

- Can not rely on hanging to dry!
- Cabinet maintenance
  - Check with manufacturer
  - Have it proceduralized

Labelling for identification post processing

- AORN: “Use a distinct visual cue to identify flexible endoscopes that are ready for use”
- SGNA: Have a system in place to for identify scopes that are clean and ready to use
- AAMI ST91 (2021): “Before it is placed in the storage cabinet, a label or tag should be attached to the processed endoscope that includes:
  - a) the processing date
  - b) the name(s) of the person(s) who performed the processing, optionally as specified by facility policy; an
  - c) expiration date, based on facility’s established risk assessment, if applicable.”

Current recommendations for length of storage “hang time”

- AORN, Multisociety Guideline, and AAMI ST91 (2021): 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: “SGNA supports a 7-day storage interval…”

FDA Safety Communications

Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication - August 4, 2015 - http://wayback.archive-it.org/7993/20170722150658/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm

Provides a list of supplemental duodenoscope reprocessing measures that facilities can use in addition to current IFUs for additional risk mitigation.

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

Microbial Surveillance

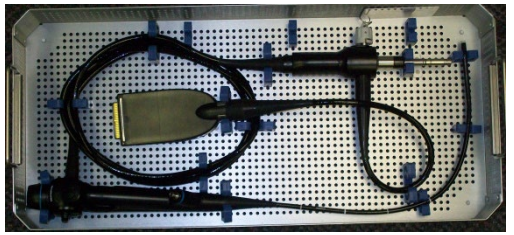
- Options include:
  - Traditional culturing
  - Gram negative test kits

- Not ATP or cleaning verification tests

- AAMI ST91 (2021): "Although the use of (microbial surveillance) is voluntary…data can be used as part of an overall quality control program". Note the FDA mandated surveillance testing that showed 5.4% of cultured scopes were positive for organisms of concern.
- AORN: "Convene an interdisciplinary team…to evaluate the need to implement…"
- SGNA: "Surveillance cultures remain the most reliable indicator of residual contamination on reprocessed endoscopes."

Sterilization of endoscopes

- Spaulding: Standard of care for critical and semi-critical devices
  - Semi-critical: If sterilization is not possible, then HLD



- More modalities compatible with surgical flexible endoscopes

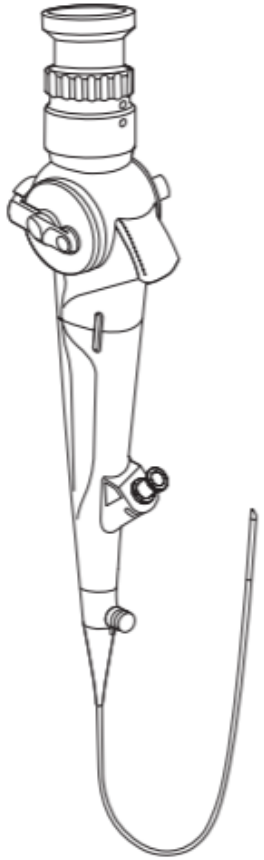
- Sterilization is dependent on adequate **cleaning, drying** and device preparation

Sterilization

- Surgical scopes - many compatible with vaporized hydrogen peroxide systems
- STERRAD in Olympus IFU
- V-Pro not in IFU - found in customer letters
- ETO compatible with all Olympus scopes
- Sterilization is dependent on adequate **cleaning, drying** and device preparation
- Store flat in wrap according to hospital policy

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



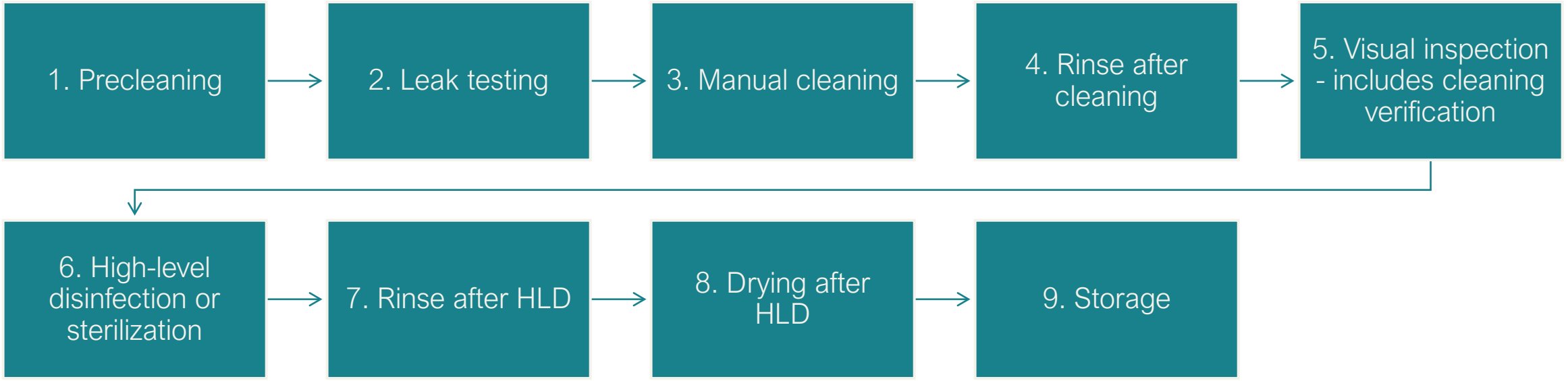
Develop an action plan for sterilization

- Inventory scopes – what models do you have
- Look at compatibility with sterilization methods
- Move all scopes that can be easily sterilized to sterilization!
    - Surgical flexible scopes: bronchoscopes, ureteroscopes, cysto, hystero, ENT, etc.
- Look at remaining scope inventory (GI scopes)
    - Prioritize by risk (e.g. duodenoscopes)
    - Based on FDA recommendations, do something
    - Sterilize, culture, liquid chemical sterilization, double HLD
- May need to adjust inventory levels of scopes

Trends and technology

- Semi- and fully-disposable endoscopes.
- Increasing number of endoscope drying modalities.
- R&D: low temperature sterilization and automated cleaning.
- Increased emphasis on bronchoscopes and other “high-risk endoscopes” - cystoscopes, duodenoscopes, endobronchial ultrasound endoscopes, linear ultrasound endoscopes, ureteroscopes.
- Aerosol and splash risks in endoscopic procedures and endoscope processing.

ENSURE BEST PRACTICE FOR ALL STEPS



Conclusion

SEEK PROVEN INFORMATION FOR BEST PRACTICE

- Standards & guidelines organizations
- Professional Societies
- Peer-reviewed literature & research

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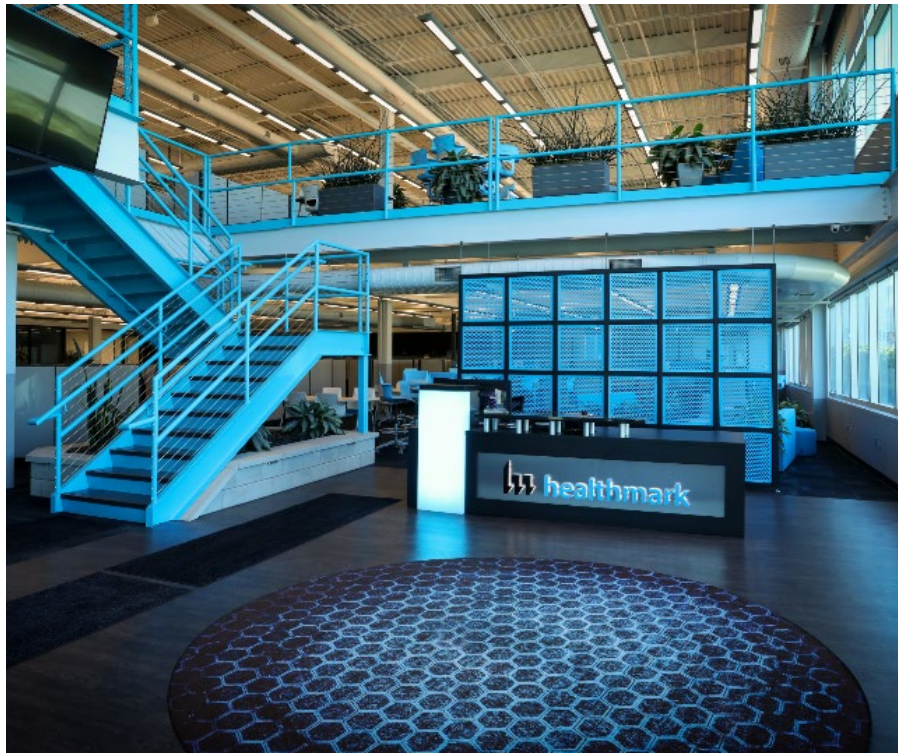

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June – See you in San Antonio for APIC!

July 16th – LTC: NHSN Reporting

August 20th – Member Presentations

October 10th – APIC-GL Fall Conference!

November 19th - TBD

Please note this schedule is subject to change. All changes and additional event details will be communicated via email, once confirmed.

Please direct questions to **Kelsey Ostergren** – kostergren@mha.org,
Chau Nguyen - chau.nguyen@corewellhealth.org, or **Denise Parr** – parrd1@michigan.gov

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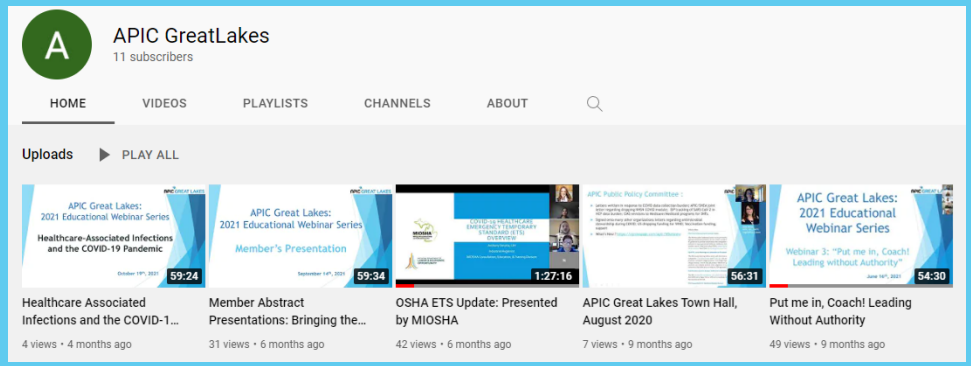

Job Postings

- **If you have an open position you would like to post to the APIC-GL webpage, please email our web master Rebecca Battjes (apicgreatlakes@gmail.com)**

Link to job board

APIC GREAT LAKES

Thank you for joining us today!