Elevator (Scope Issues) Going Up!

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Objectives

- Identify two reasons why elevator scopes have a higher risk than other scopes of being linked to a “true outbreak”
- List 4 ways to validate scope cleaning and limitations of each
- List 4 things to look for while validating scope cleaning
- Describe 1 limitation of each cleaning validation approach

Recent Outbreaks with Adherence to Manufacturer's Instructions and Professional Guidelines

- Presence of an unusual pathogen that resulted in an investigation and recognition that duodenoscopes were the source of the outbreak
  - Epstein et al. JAMA 2014;312:1447-1455 (NE IL)
  - Wendorf et al. ICHE 2015 (Seattle- mortality 50% for CRE)
  - At least four other CRE outbreaks related to ERCP
    - UCLA Ronald Reagan Medical Center
    - Cedar Sinai Medical Center
    - Another LA hospital
    - University of Pittsburgh Medical Center
    - Wisconsin medical facility

Why ERCP (Endoscopic Retrograde Cholangiopancreatography)?

- More than 500,000 ERCP procedures using duodenoscopes are performed in the US annually
- Procedure is the least invasive way of draining fluids from the pancreatic and biliary ducts blocked by cancerous tumors, gallstones or other conditions
- Complex design of duodenoscopes causes challenges for cleaning and HLD. Some parts of the scope are extremely difficult to assess and effective cleaning of all areas of the duodenoscope may not be possible.

What are we talking about here?

- ERCP scopes
  - Procedures tend to be more bloody than most scopes
  - More "action" than most scopes (use of channels and manipulations)
  - Used in a population that has most likely had extensive healthcare encounters
  - The basket function is problematic in cleaning
  - More "outbreaks" than other scopes per use
    - Actual deaths linked to these scopes
    - "Normal" complication is bacteremia

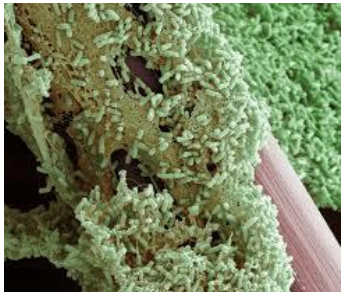
Elevator Scopes

- EUS also uses an elevator
  - Outbreak has been associated these
  - FDA group said ERCP=EUS
    - But subsequent documents did not make the link

Challenges (This slide was stolen from Christie Chapman and modified slightly by me)

- Complex design of equipment, particularly ERCP and EUS
- Reprocessing detailed, multi-step process
- Processing space may be limited
- Time constraints – scope turnaround time
- Regulatory guidelines conflicting

- Flexible endoscopes acquire high levels of bioburden because of the cavities they enter
  - CDC reports that the bioburden found on flexible gastrointestinal endoscopes after use can be as high as 10,000,000,000 (that's billion folks), with the highest levels found in the suction channels
  - CFU for surgical instruments were generally in the 100s
- Even with full adherence to reprocessing protocols, endoscopes may remain contaminated with pathogenic microorganisms

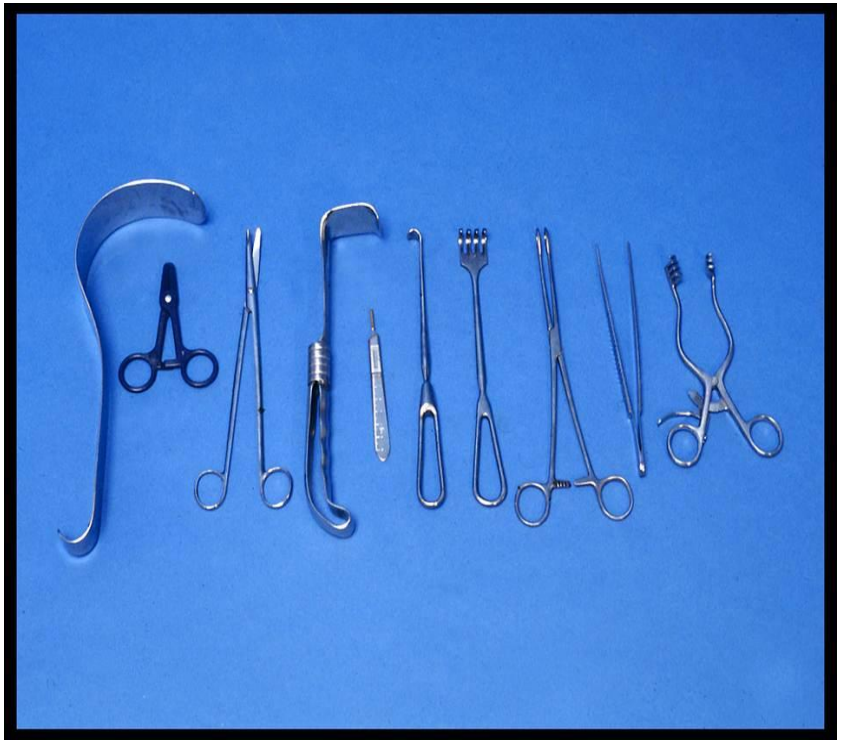


CDC, Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

ENDOSCOPE REPROCESSING: CHALLENGES

Complex [elevator channel]-$10^{7\text{-}10}$ bacteria/endoscope

Surgical instruments-$<10^{2}$ bacteria



Reason for Endoscope-Related Outbreaks

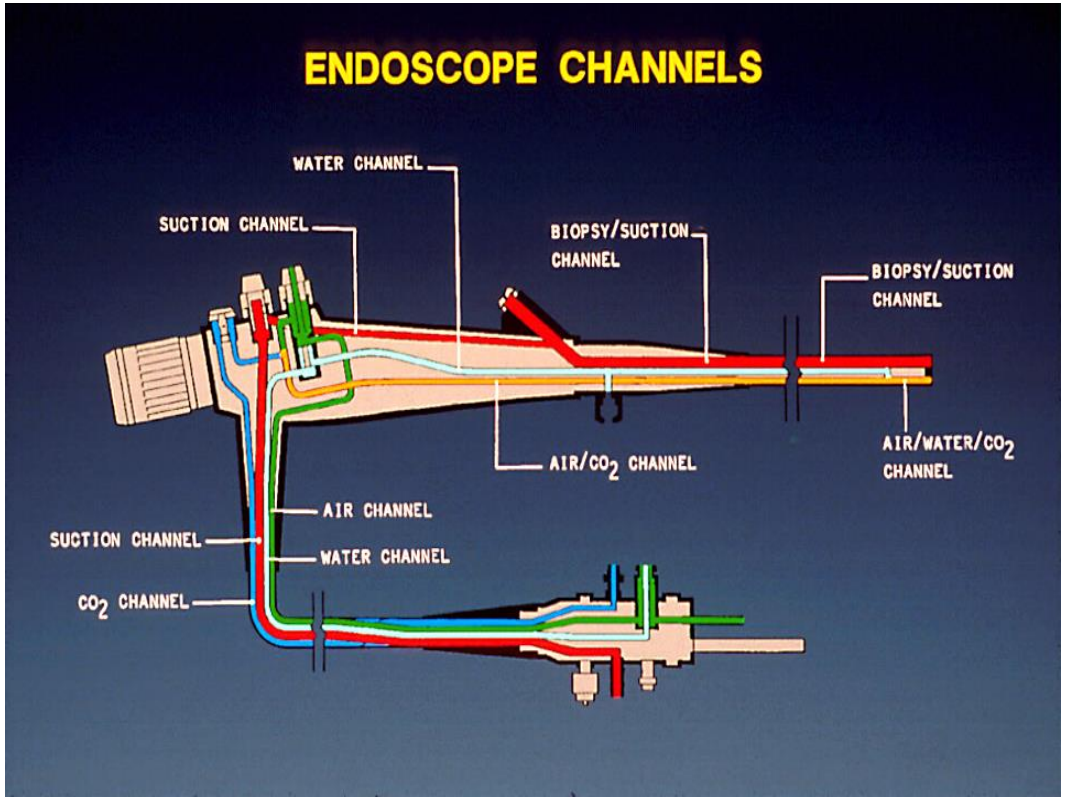
Rutala WA, Weber WA. Infect Control Hosp Epidemiol 2015

- Margin of safety with endoscope reprocessing minimal or non-existent for two reasons:
- Microbial load
  - GI endoscopes contain $10^{7\text{-}10}$
  - Cleaning results in 2-6 $\log_{10}$ reduction
  - High-level disinfection results in 4-6 $\log_{10}$ reduction
  - Results in a total 6-12 $\log_{10}$ reduction of microbes
  - Level of contamination after processing: 4 $\log_{10}$ (maximum contamination, minimal cleaning/HLD)
- Complexity of endoscope

FEATURES OF ENDOSCOPES THAT PREDISPOSE TO DISINFECTION FAILURES

Rutala WA, Weber WA. Infect Control Hosp Epidemiol 2015

- Heat labile
- Long, narrow lumens
- Right angle bends
- Rough or pitted surfaces
- Springs and valves
- Damaged channels may impede microbial exposure to HLD
- Heavily contaminated with pathogens, 10^{7-10}
- Cleaning (2-6 $\log_{10}$ reduction) and HLD (4-6 $\log_{10}$ reduction) essential for patient safe instrument



The process of HLD failure

- Reprocessing semicritical items has been shown to have a narrow margin of safety
- **Narrowest margin of safety attributed to high microbial load and complex instruments with lumens**
- Any deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection
- **Problems encountered with reprocessing semicritical equipment often related to improper cleaning**

Reprocessing Channeled Endoscopes

Rutala, Gergen, Bringhurst, Weber. 2015

Exposure Method	VRE Contamination Before HLD (glutaraldehyde)	VRE Contamination After HLD
Passive HLD (immersed, not perfused)	$3.6x10^8$ $2.0x10^8$ $1.1x10^8$	$7.5x10^8$ $1.0x10^8$ $6.8x10^7$
Active HLD (perfused HLD into channel with syringe)	$8.4x10^7$ $1.5x10^8$ $2.8x10^8$	1 CFU 0 0

- Pathogens must have exposure to HLD for inactivation
- Immersed channeled flexible scope into HLD will not inactivate channel pathogens
- Completely immersed the endoscope in HLD and ensure all channels are perfused
- Air pressure in channel stronger than fluid pressure at fluid-air interface (you can still have perfusion is even if AER is trying to flush)

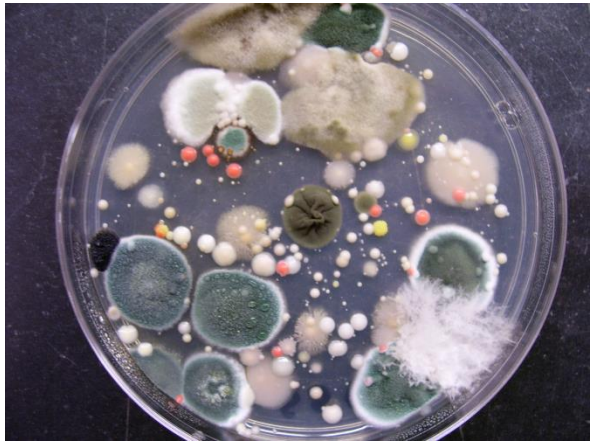
Surveillance for ERCP/EUS infections

- Poor
  - Dependent on rare organisms for outbreak finds
  - Pan sensitive E. coli outbreaks would be almost impossible to identify
- HIV, hepatitis B and hepatitis C outbreaks are unheard of (but where we spent most of our energy)
- Retrospective look back on MDROs
- DNA analysis clearly proves this is an issue

“There can be no disinfection or sterilization without cleaning”

- Cleaning Validation approaches
  - Culture
  - ATP
  - Assay
  - Visual Inspection

Cultures as Validation



- Advantages
  - "Gold Standard"
  - "Proves" the presence of viable organisms
- Disadvantages
  - False negative results
  - Some organisms are not of concern (Staph epi)
  - Delay lasts up to 3 days
    - Can redo process after culture is obtained so culture means "nothing" and you can immediately release scope for use
  - Two person process
  - Hospitals can not do environmental culturing (cost or competence)
  - What do you do on first culture result if positive?
  - Extrapolates sterility as standard for cleaning

ATP as Validation

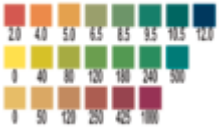
- Advantages
  - "Validated" in the literature
  - Quick
- Disadvantages
  - Cut points arbitrary
  - Temperature sensitivity
  - No correlation with culture results
  - Need sterile water
  - ATP <200 RLU benchmark for clean, equates to <4 $\log_{10}$ CFUs/cm^2 or 10^6 CFUs per endoscope Thus, an endoscope assessed as clean using ATP could still have a significant microbial load (e.g., 10^6)

Adenosine Triphosphate (ATP) Validation

Alfa et al. Am J Infect Control 2013;41:245

- Validated as a monitoring tool for assessing cleaning because it detects organic residuals
- ATP is not a good indicator of microbial contamination and has not been validated as a method to assess the risk of patient-to-patient transmission

Residue Assay as Validation



- Advantages
  - Cheapest approach
  - Quick
- Disadvantages
  - Not correlated with cultures
  - Need sterile water
  - Can't have a color blind reader

Scope Visualization

- Advantages
  - You can see inside the scope
  - Quick
- Disadvantages
  - If they put dirty surgical instruments in a tray……..
  - Microbial contamination is not visible

Guideline (Year released)	Cleaning validation of Endoscope Reprocessing (culturing, ATP or Assay)
AAMI ST91:2015 (2015)	All scopes: "The use of methods that are able to quantitatively or chemically detect organic residues that are not detectable using visual inspection should be considered and included in facility policies and procedures on device cleaning." (Page 39)
AORN (2008)	Periodic testing of cleaning methods. Tests not specified. Under review for publication early 2016.
ASGE 2015 (interim dated 3/17/2015)	Consider culture ATP and assay unresolved (Page 4)
CDC (2015 & 2008)	Consider culture in non outbreak setting (2015) Recommended Culturing in outbreak situations ATP and Assay unresolved issue (2015) HICPAC did not recommend institution of routine surveillance culturing in the U.S
ECRI (2015)	Recommend culturing (page 2) ATP and assay not addressed
FDA	Hospitals and health care facilities must do an assessment if they are utilizing duodenoscopes. In addition to meticulously following manufacturer reprocessing instructions for use (IFUs),may take one or more of these additional steps to further reduce the risk of infection and increase the safety of these medical devices." • "Those steps to be considered are: Microbiological Culturing Ethylene Oxide Sterilization Use of a Liquid Chemical Sterilant Processing System Repeat High-Level Disinfection" "Surveillance culture results take time to produce. When duodenoscopes are cultured after every reprocessing cycle, the duodenoscope is typically quarantined and not available for use until culture results are known." "Furthermore, these measures may not be feasible in all health care facilities and each of these options comes with its own benefits and limitations."

Cleaning Validation Other guidelines

Multi Society Guidelines (ASGE, SHEA, APIC) (2011)

- **All scopes: Unresolved (Page 1075)**

SGNA (2013)

- Not addressed

Sterilize the Dang Scopes!

- Advantages
  - Kill is several logs greater
  - Stopped several outbreaks
- Disadvantages
  - Takes longer
  - More expensive
  - No sterilization without cleaning
    - Bore out failures in hydrogen peroxide plasma literature no reason to expect ETO or paracetic acid literature
    - If the mechanism of kill depends on contact does it seem reasonable to expect a biofilm to allow contact with all viable organisms?
  - Scope failures post ETO

Guideline (Year released)	Sterilization of Elevator scopes (ECRP & EUS)
AAMI ST91:2015 (2015)	All scopes: Preferred method when allowed by IFU. (Page 28)
AORN (2008)	HLD or sterilization. Under review for 2016.
ASGE 2015 (interim dated 3/17/2015)	Consider (Page 3)
CDC (2015 & 2008)	Not addressed in 2015 or 2008 guidelines
ECRI (2015)	Not addressed
FDA	Hospitals and health care facilities must do an assessment if they are utilizing duodenoscopes. In addition to meticulously following manufacturer reprocessing instructions for use (IFUs),may take one or more of (these additional steps to further reduce the risk of infection and increase the safety of these medical devices. • Those steps to be considered are: • " Microbiological Culturing • Ethylene Oxide Sterilization • Use of a Liquid Chemical Sterilant Processing System • Repeat High-Level Disinfection" "Furthermore, these measures may not be feasible in all health care facilities and each of these options comes with its own benefits and limitations."

Sterilization and scopes other guidelines

Multi Society Guidelines (ASGE, SHEA, APIC) (2011)

- **Not addressed**

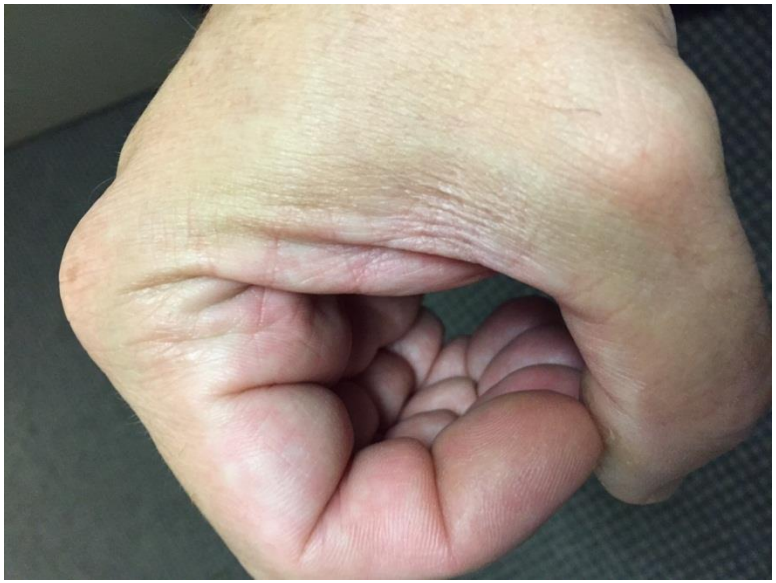
SGNA (2013)

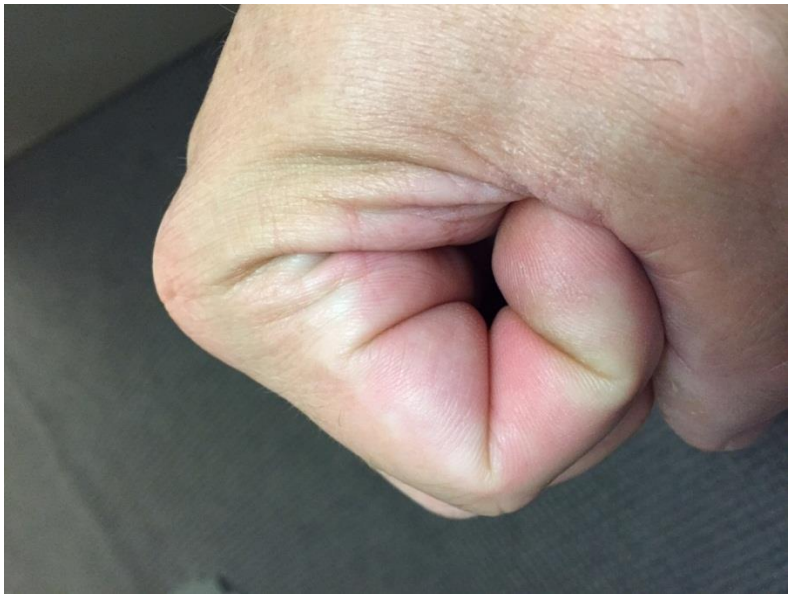
- Not within the scope of the article

Checklist for scope observation

1) Ask for current Instructions for use (IFU) for scope and ask how they know it is current.
2) Review the person has a competency for that scope
3) Determine if scope has channel(s)
4) Assure scope is wiped down at bedside on all sides (if not using a sponge with 360 degree coverage of lumen then make sure you see all of the exterior lumen cleaned).
5) Assure scope is transferred in a solid container to the room where enzymatic cleaning occurs
6) Make sure the enzymatic cleaner and water is measured to correct concentration. Validate the measuring.
7) Assure the dirty scope is never laid on the clean side.

Point 4 review





Part 2

8) If channeled, assure brush is the brush defined in the IFU if not make sure manufacturer has a claim for that scope.

- Brushing should occur and adequate number of times to assure cleaning. (Can once ever be enough?)
- When the brush is withdrawn is it visually inspected?
- Is the entire brush inspected? (360 degrees)
- Is their adequate light to do the inspections and is their some assurance of visual acuity (magnifying glass x 10 in CDC document, readers? et cetera)

9) If the IFU has a time (i.e. 30 seconds) that a step takes, are time pieces used to measure that time?

10) Are all steps in the IFU done in the order listed?

Part 3

11) Is the temperature in the room within the range of the HLD and the enzymatic cleaner?

12) If an AER (sterilizer or HLD) is used

- Ask how the users knows that the High level disinfectant (HLD)or sterilizing fluid is flowing through to the connection (Do NOT rely on alarms, there should be a visual test of flow)
- Ask to see AER description of how caps and valves and other small separate pieces are to be put in AER and assure if that is compliant with practice

13) Validate test strips are not expired (test strips expire based on date opened not expiration date)

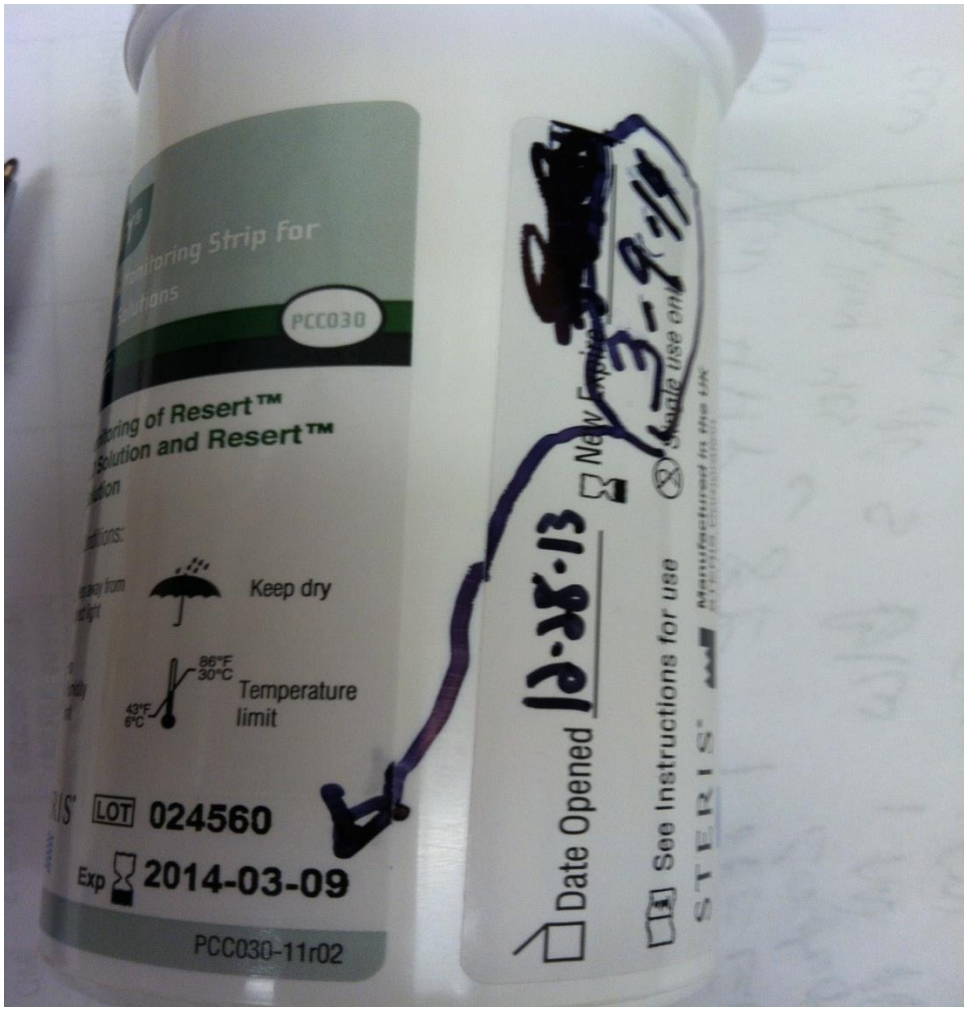
More stuff (4)

14) If manual HLD is done:

- Document scope name and model and assure that Kim is aware after the fact
- Get steps and watch all steps (literature shows only 1% of time this happens)
- Validate test strips are not expired (test strips expire based on date opened not expiration date)

15) For channeled scopes:

- Assure that the channel has an alcohol blow through and a medical air gas blow through. The amount of alcohol to be used is in the scopes IFU. If an AER is used it may have a cycle that does that.
- The scope should not be dripping when the process is complete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Keep dry
Temperature limit
LOT 024560
Exp 2014-03-09
PCC030-11r02
Date Opened
See Instructions for use
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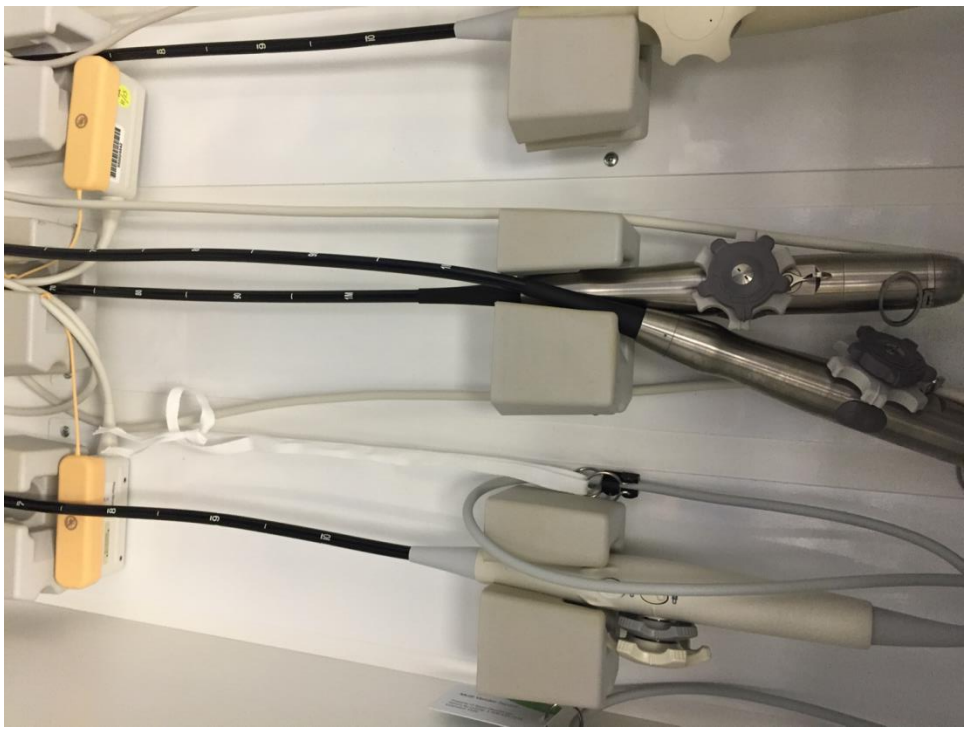

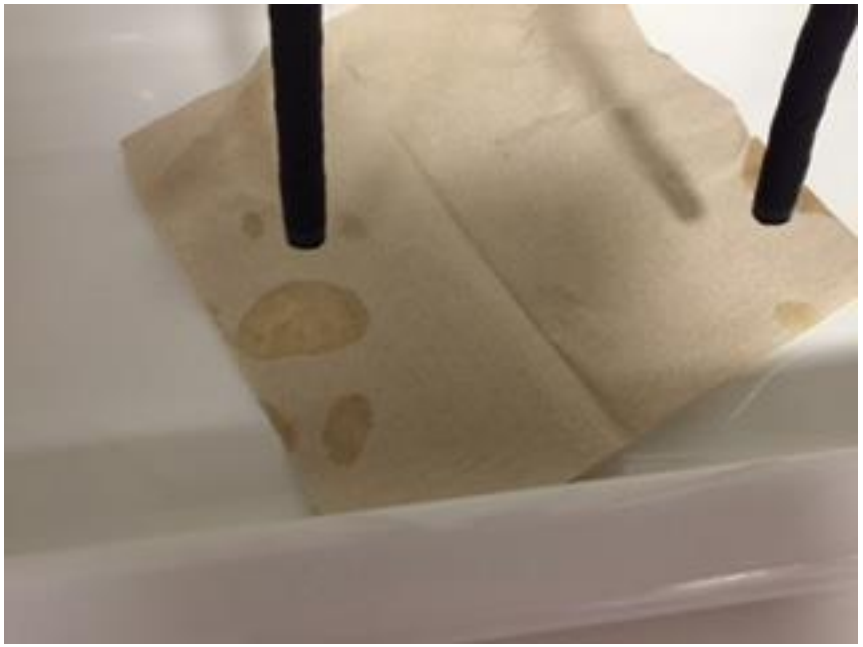

5 Observations

16) Valves should not be placed on scope being placed in storage but kept with the scope

17) Was hand hygiene preformed between handling dirty scope and before placement in cabinet?

18) Storage in cabinet should not touch cabinet wall or other scopes nor should visible fluids or staining be present in the scope cabinet

Current Enhanced Methods for Reprocessing Duodenoscopes

Rutala WA, Weber WA. Infect Control Hosp Epidemiol 2015

Hospitals performing ERCPs should do one of the following (priority ranked); doing nothing is not an option:

- **Ethylene oxide sterilization after high level disinfection with periodic microbiologic surveillance**
- **Double high-level disinfection with periodic microbiologic surveillance**
- **High-level disinfection with scope quarantine until negative culture**
- **Liquid chemical sterilant processing system using peracetic acid (rinsed with extensively treated potable water) with periodic microbiologic surveillance**
- **High-level disinfection with periodic microbiologic surveillance**

UNC Hospitals
Rutala Response to ERCP Outbreaks

- Ensure endoscopes are reprocessed in compliance with national guidelines (CDC, ASGE, etc)
- Evaluate CRE culture-positive patients for ERCP exposure
- In the short term, enhance reprocessing of ERCP scopes Reprocess ERCP scopes by HLD followed for ETO sterilization
- Microbiologic surveillance, 5-10% of scopes monthly
- When new recommendations are available from ASGE, CDC, FDA, etc. comply

Potential Future Methods to Prevent GI-Endoscope Related Outbreaks

Rutala WA, Weber WA. Infect Control Hosp Epidemiol 2015

- Steam sterilization for GI endoscopes
- New low temperature sterilization methods proving SAL 10^{-6} achieved (or optimizing current LTST)
- Disposable sterile GI endoscopes
- Improved GI endoscope design (to reduce or eliminate challenges listed above)
- Use of non-endoscope methods to diagnosis or treat disease (e.g., capsule endoscopy, blood tests to detect GI cancer, stool DNA test)

Some Potential Sterilization Technologies for Duodenoscopes

Rutala WA, Weber WA. Infect Control Hosp Epidemiol 2015

- Optimize existing low-temperature sterilization technology
  - Hydrogen peroxide gas plasma
  - Vaporized hydrogen peroxide
  - Ethylene oxide
- Potential new low-temperature sterilization technology
  - Ozone plus hydrogen peroxide vapor
  - Nitrogen dioxide
  - Supercritical CO_2
  - Peracetic acid vapor
- Steam sterilization for heat-resistant endoscopes

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Rutala WA, Weber WA. Infect Control Hosp Epidemiol 2015, In press

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ERCP Scopes: What Can We Do To Prevent Infections?

- Review the CRE/MDR outbreaks associated with ERCP procedures
- Evaluate the cause of endoscope-related outbreaks
- Discuss the alternatives exist today that might improve the safety margin associated with duodenoscope reprocessing
- Describe how to prevent future outbreaks associated with duodenoscopes and other GI endoscopes
- Identify how FDA can facilitate a shift from HLD to sterilization

ERCP Scopes: What Can We Do To Prevent Infections?

- **Endoscopes represent a nosocomial hazard. Narrow or nonexistent margin of safety associated with high-level disinfection of semicritical items due to microbial load and complexity (biofilms?).**
- **Hospital must select 1 of the 5 enhanced methods for duodenoscope reprocessing. Doing nothing is not an option.**
- **To protect the public health and prevent ERCP-related outbreaks, there is an urgent need to shift from HLD to sterilization.**
- **FDA (and professional organizations) should modify the Spaulding classification to require sterilization of instruments that directly or secondarily enter normally sterile tissue.**
- **Manufacturers that submit instruments to FDA for clearance that secondarily enter normally sterile tissue need to offer a sterilization method. This will prevent ERCP-related outbreaks.**

Are Elevator Scopes Safer Today Than Yesterday?

- Yes
  - Increased awareness
  - Increased competency
  - More attention by Infection Preventionists
  - Better understanding of the importance of the process by all parties
    - Physicians more aware that pushing for quick turnaround is bad for the patient

Are Elevator Scopes Safer Today Than Yesterday?

- No
  - No real solutions to the process exist
  - IFU changes by Olympus is on third run through (1 released this week with a new brush!)
  - So many different recommendations means no standardization
  - The problem isn't the people, it is the design of the scopes and that has not changed

Guidelines online

[i] http://www.tsge.org/index.php?option=com_lyftenbloggie&view=entry&category=legislative&id=2%3Ainterim-guidance-transmission-of-cre-via-ercp&Itemid=139

[ii] http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html

[iii] http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM445592.pdf

[iv] https://www.ecri.org/resource-center/Pages/Superbug.aspx

[v] http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM447407.pdf

[vi] http://www.asge.org/uploadedFiles/Public_E-Blast_PDFs/ReprocessingEndoscopes.pdf

[vii] http://www.sgna.org/Portals/0/Education/PDF/Standards-Guidelines/SGNA_HLDGuideline13.pdf