



Disclosures

- **Successful completion:** Participants must complete the entire program and submit required documentation. No partial credit will be given.
- **Conflict of interest:** Employee of STERIS.
- **Commercial company support:** Fees are underwritten by education funding provided by STERIS.
- **Non-commercial company support:** None.
- **Alternative/Complementary therapy:** None.

Continuing Education

- STERIS Corporation is an approved provider of continuing education by California Board of Nursing (provider # CEP 11681) and the Board of Ambulatory Surgery Certification (provider # 1417).
- This program is approved for:
 - **1.5** hour(s) of GI specific content credit by American Board of Certification for Gastroenterology Nurses (ABCGN)
 - **1.5** AEU(s) & **1.5** IPCH(s) by BASC
 - **1.5** contact hour(s) of continuing education credit
 - HSPA
 - CBSPD
 - CBRN

Continuing Education



The Leader in Perioperative Certification

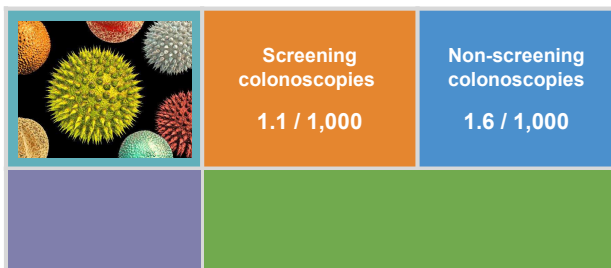
Through a partnership with CCI®, it also meets CNOR® and CSSM® recertification requirements for perioperative nurses.

Learning Objectives

- Describe microbiology challenges related to flexible endoscope processing
- Recognize processing errors that could lead to infection and implement strategies to mitigate them



Surprising Infection Rates Of Endoscopy



10 Year Review Of Gastrointestinal Outbreaks

Root Cause

- Insufficient Drying
- Inadequate cleaning
- Inadequate high-level disinfection
- Biofilm formation

Microorganisms

- *Klebsiella pneumoniae*
- *Pseudomonas aeruginosa*
- *Escherichia coli*
- *Salmonella enteritidis*

All Flexible Endoscopes

MAUDE Report Key 2818381 (2012) - Cystoscopy

- No point of use treatment
- No leak testing of scope
- Improper cleaning
- Incorrectly performed manual HLD

MAUDE Report Key 7272402 (2018) - Bronchoscopy

- Incorrect point of use treatment
- Incorrect leak test
- Incorrect cleaning
- Incorrect use of AER

Points Of Transmission

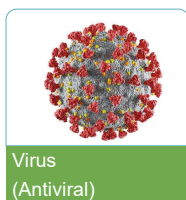
Infected person



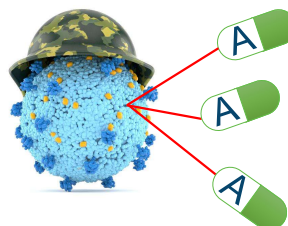
Environment



Types Of Microorganisms



Antibiotic Resistance



- Methicillin-resistant *Staphylococcus aureus* (MRSA)
- Carbapenem-resistant *Enterobacteriaceae* sp. (CRE)
- New Delhi metallo- β -lactamase-1 *Escherichia coli*



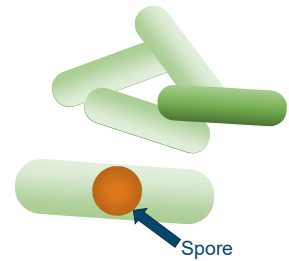
≠

High level disinfectant
or sterilant resistance

Challenging Organisms To Decontamination

ENDOSPORE

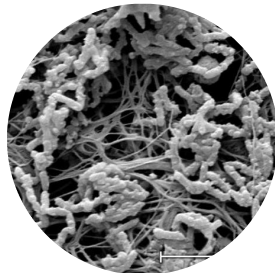
- Dormant form
- Resistant to harsh conditions
- Resistant to chemicals
- Few bacteria strain make endospores
- Clostridioides difficile (C. diff.)



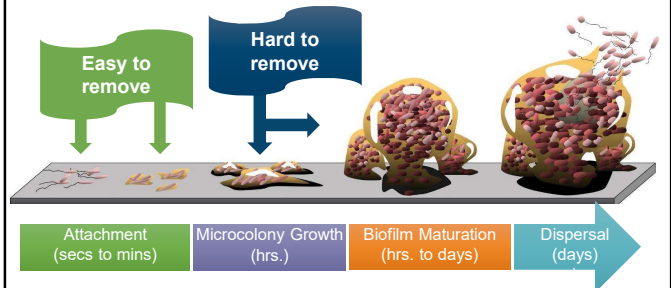
Challenging Organisms To Decontamination

Biofilms

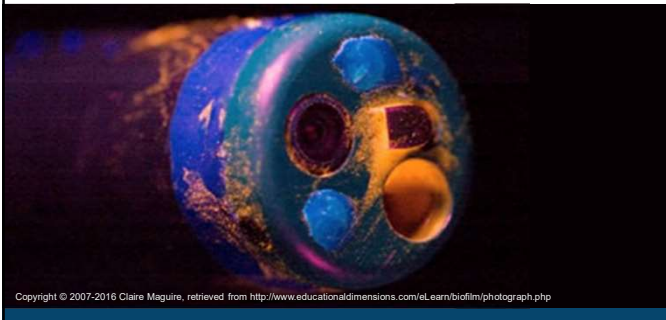
- Microbial colonies
- Extracellular Polymeric Substance (EPS)
- Protective barrier
- Pseudomonas species



How Biofilm Forms



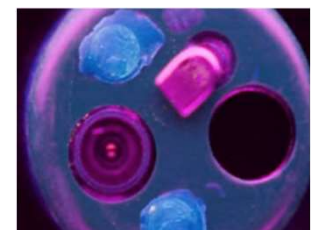
Effect Of Mature Biofilm



Biofilm After Cleaning And High Level Disinfection

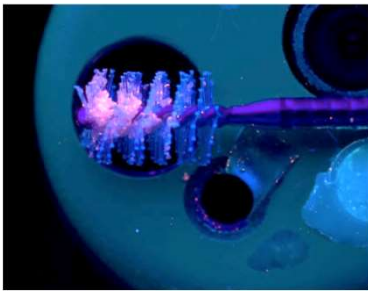


After HLD with glutaraldehyde



After HLD with PAA

Mature Biofilm Within Un-brushable Channels

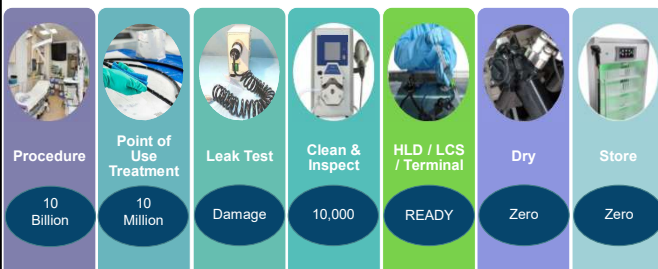


After brushing
air/water channel



Processing Challenges Leading
To Cross Contamination

The Rise & Fall Of Endoscope Contamination

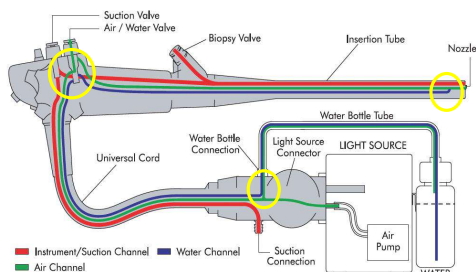


Success of each step depends on successful completion of previous the step

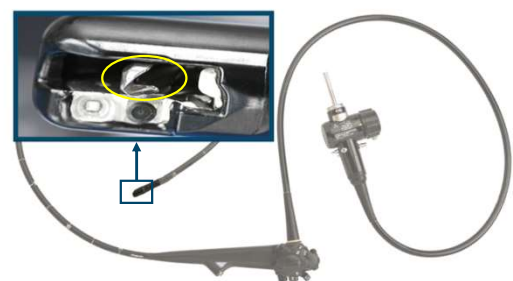
Sources Of Contamination



Challenges In Endoscope Processing: Design



Challenges In endoscope Processing: Forceps Elevator



Forceps Elevator Mechanism Close-up



Challenges In Endoscope Processing: Forceps Elevator

Cleaning considerations

• Three positions to clean

- Up
- Down
- Middle



HLD/LCS considerations

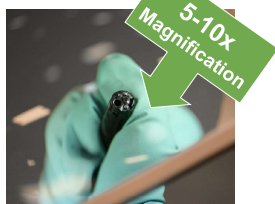
• Flow Adapters / Connectors

• 45° angle for some



Challenges In Endoscope Processing: Undetected Damage & Debris

- Complete these steps immediately after manual cleaning!
- Inspect for:
 - Debris
 - Damage
 - Integrity of seals/gaskets
 - Lens clarity
 - Function of knobs & switches



Challenges In Endoscope Processing: Undetected Problems

"Methods that are able to quantitatively or chemically detect organic residues that are not detectable using visual inspection should be implemented." (ANSI/AAMI ST91, 2021)

- After cleaning and rinsing
- High Risk Endoscopes – Every time
- All others – at facility established intervals

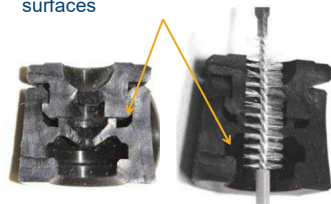
High risk examples:

- Duodenoscope
- Bronchoscope
- Ureteroscope

Challenges In Endoscope Processing: Reusable Valves

1

Brush can't reach valve surfaces



2

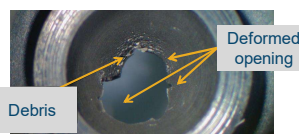
Contamination grew viable bacteria



Challenges In Endoscope Processing: Reusable Valves

1

- Lumen is deformed
- Damage can't be cleaned
- Damage provides reservoir for microbes



2

- Microscopic damage leads to contamination



Alternatives To Reusable Accessories

Procedure Kits 	Connectors 	Water Bottle Adapters & Irrigation Tubing 
Valves 		



Challenges In Endoscope Processing: Failure To Dry

47% of endoscopes had residual moisture after 24+ hours of storage

Ofstead et al (2016)

47% of endoscopes had residual moisture after 24+ hours of storage



Strategies To Prevent Infection Transmission

Chain Of Infection

Tools to Break the Chain

- Point of use treatment
- Contained transportation
- Decontamination
- Single use accessories
- Drying
- Storage
- Maintenance

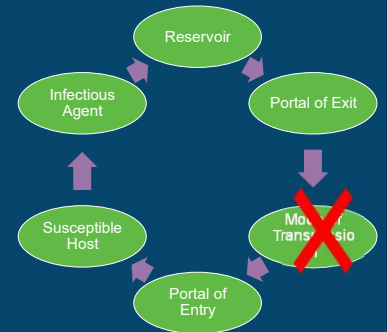
The Bug Stops Here

```
graph TD; Reservoir([Reservoir]) --> PortalExit([Portal of Exit]); PortalExit --> ModeTransmission([Mode of Transmission]); ModeTransmission --> PortalEntry([Portal of Entry]); PortalEntry --> SusceptibleHost([Susceptible Host]); SusceptibleHost --> InfectiousAgent([Infectious Agent]); InfectiousAgent --> Reservoir;
```

The diagram illustrates the Chain of Infection. It consists of six green ovals connected by purple arrows in a clockwise cycle: Reservoir, Portal of Exit, Mode of Transmission, Portal of Entry, Susceptible Host, and Infectious Agent. A large red 'X' is superimposed over the 'Mode of Transmission' oval, indicating that this is the point where the bug stops.

- Point of use treatment
- Contained transportation
- Decontamination
- Single use accessories
- Drying
- Storage
- Maintenance

The Bug Stops Here



Point Of Use Treatment

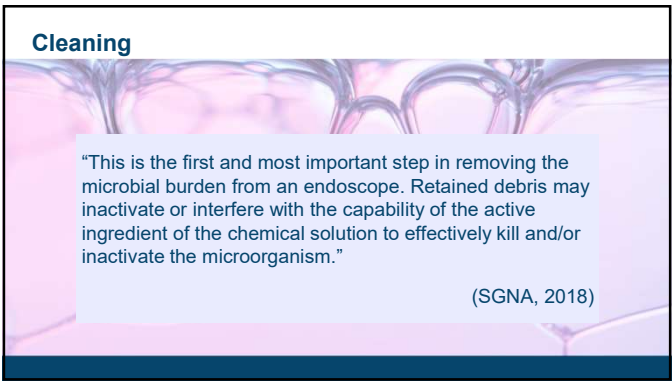
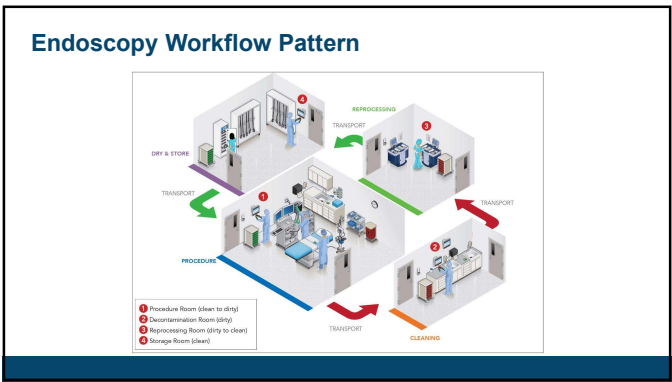
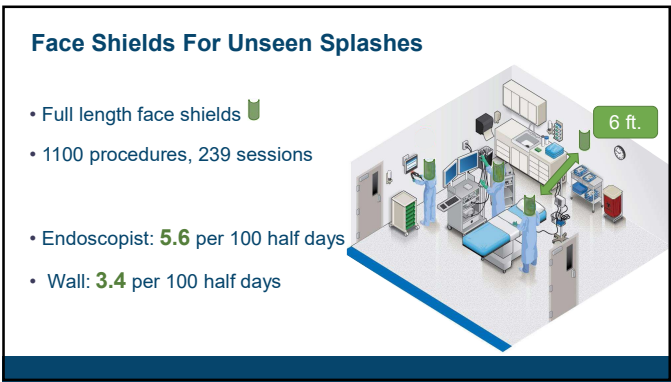
Proper point of use treatment can decrease bacteria level by billions of CFU/cm²!



Contained Transport Of Flexible endoscopes

Rigid transport tray and liner





Cleaning Chemistries

AORN 2021 Selecting Cleaning Chemistry

- Compatible and non-abrasive
- Low foaming
- Easily removed during rinsing
- Non-toxic in use solution
- Effective on clinically relevant soils
- Provides soil dispersion
- Biodegradable and environmental preferable
- Cost effective with a long shelf life

Endoscopy Cleaning Chemistry Considerations

- Neutral Detergent (with or without enzymes)
- Dilution rate
- Temperature
- Contact time
- Storage conditions
- Shelf and Use life

New freshly-prepared cleaning solution for each flexible endoscope

Cleaning Chemistry Formulations

- Water
 - Largest component
- Surfactant
 - Decrease surface tension
 - "Wetting" agent
- Enzyme
 - Breaks down specific soil components
- Buffer
 - Controls pH
- Chelating Agent
 - Sequesters metal ions

High Level Disinfectants And Sterilants

High Level Disinfection	Liquid Chemical Sterilization	Terminal Sterilization
Kills all pathogenic microorganisms except high levels of endospores	Kills all microorganisms including high levels of endospores	Kills all microorganisms including high levels of endospores
Rinsing required	Rinsing required	Aeration may be required
Not sterile	No Sterile Storage	Sterile storage

Choosing A Biocidal Process

- Based on Risk Assessment
 - High-risk endoscope
 - Patient population
 - Infection rates
 - Outbreak organisms



Water

Water Use	Type of Water Required
Making Cleaning Solution	Utility Water
Rinse Water Following Cleaning	Utility Water
HLD or LCS Solution	Critical Water
Rinse Water following HLD or LCS	Critical or Sterile Water

AORN Guidelines for Perioperative Practice "Flexible Endoscopes", 2021

Alcohol – Channel Drying Assistance

- 60-90% ethyl or isopropyl alcohol
- Endoscope manufacturer's IFU
- Isopropyl is fixative



Dry Before Storage

External

- Remove from AER
- Fresh non-linting cloth
- Clear crevices /recesses

Internal

- No Drip Dry
- ≥ 10-minutes channel drying
- Instrument or HEPA filtered Air
- Drying Cabinet

Wet valves = contamination

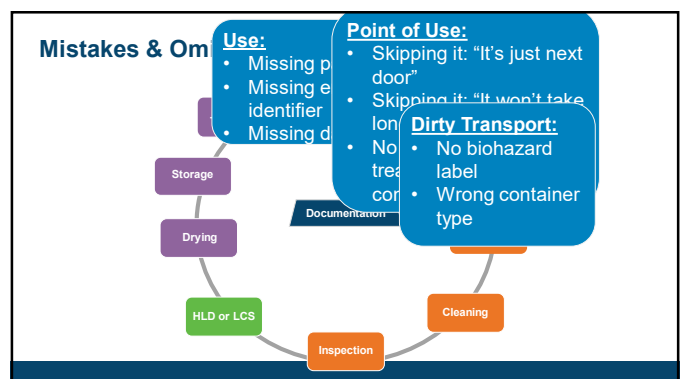
Air Types

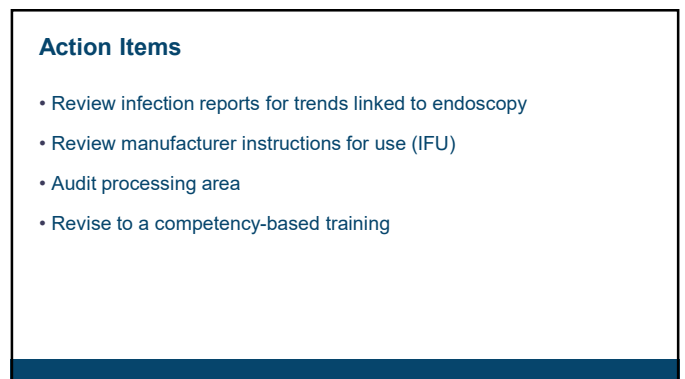
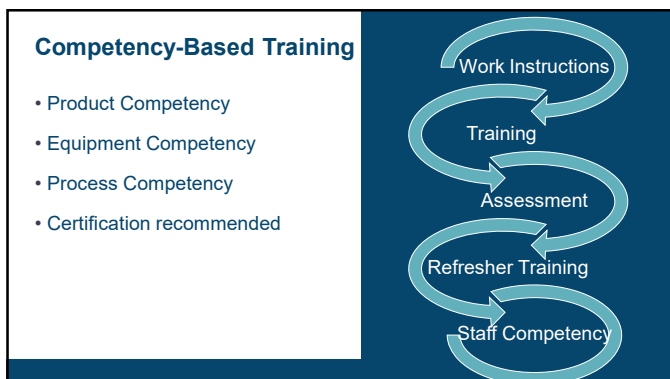
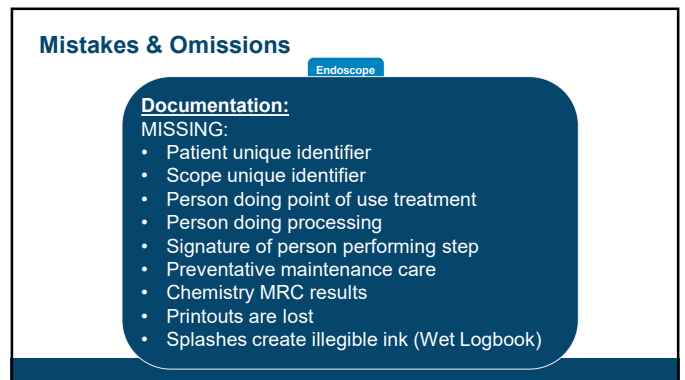
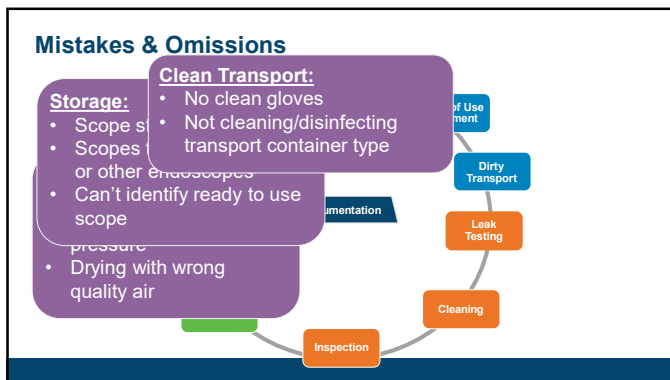
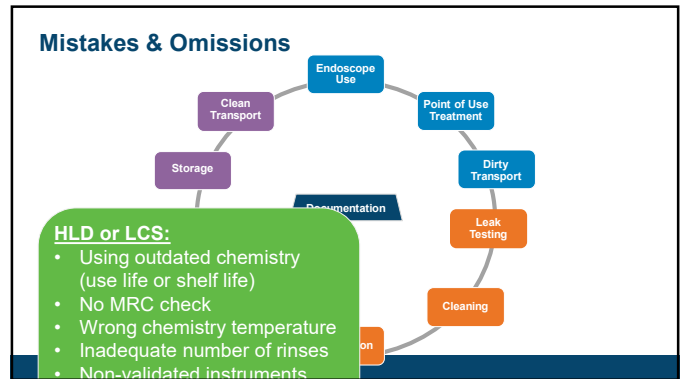
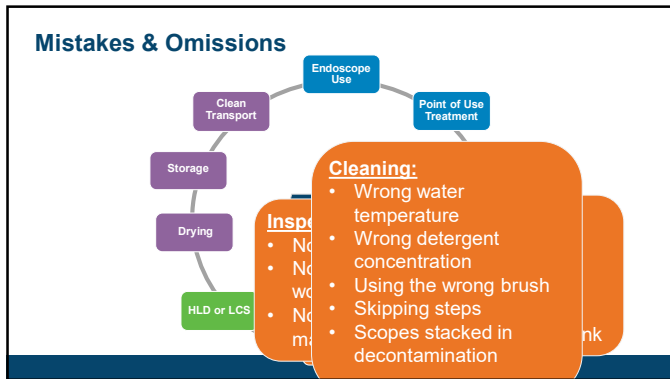
HEPA Filtered Air

- 0.3-micron filtration
- H13 or H14 grade
- Typically, room temperature and humidity

Instrument Air

- 0.01-micron filtration
- ANSI/ISA S-7.0.01 Quality standard for instrument air
- No water droplets or hydrocarbon vapors





References

- Alfa, M.J., Degagne, P., & Olson, N. (1999). Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning. *American Journal of Infection Control*, 27(5), 392-401. doi: 10.1016/s0196-6553(99)70004-0.
- American National Standards (ANSI) (1996) ANSI/ISA S-7.0.01 Quality standard for instrument air. Research Triangle Park, NC ISBN: 1-55617-606-6
- AORN (2022) Guidelines for Perioperative Practice. Denver, CO:AORN
- Association for the Advancement of Medical Instrumentation. (2021). AAMI/ANSI ST91:2021 Flexible and semi-rigid endoscope processing in health care facilities. Arlington, VA: AAMI.
- Eakins, Andy (2016) Superbugs and traceability of endoscope valves. *ENDOPRO Magazine*, 1(6), 27-32.
- Epstein L, Hunter JC, Arwady MA, Tsai V, Stein L, Gribogiannis M, Frias M, Guh AY, Laufer AS, Black S, Pacilli M, Moulton-Meissner H, Rasheed JK, Avilian JJ, Kitchel B, Limbago BM, MacCannell D, Lonsway D, Noble-Wang J, Conway J, Conover C, Vernon M, Kallen AJ. (2014) New Delhi metallo- β -lactamase-producing carbapenem-resistant *Escherichia coli* associated with exposure to duodenoscopes. *JAMA*. 8;312(14):1447-55. doi: 10.1001/jama.2014.12720. PMID: 25291580

References

- FDA MAUDE reports Key 2818381. (2012). MAUDE Adverse Event Report: Olympus Medical Systems Corporation, Olympus OES Cystonephrofiberscope cystoscope. Retrieved from https://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=2818381
- FDA MAUDE reports Key 2818381. (2012). MAUDE Adverse Event Report: Olympus Medical Systems Corporation, Olympus OER-PRO bronchoscope. Retrieved from https://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=7272402&pc=FEB
- Johani, Khalid & Hu, Honghua & Santos, L. & Schiller, Sabine & Deva, Anand & Whiteley, Greg & Almatroudi, Ahmad & Vickery, Karen. (2018). Determination of bacterial species present in biofilm contaminating the channels of clinical endoscopes. *Infection, Disease & Health*. 23. 10.1016/j.idh.2018.06.003.
- Johnston, E.R., Habib-Bein, N., Dueker, J.M., Quiroz, B., Corsaro, E., Ambrogio, M., Kingsley, M., Papachristou, G.I., Kreiss, C., & Khalid, A. (2018). Risk of bacterial exposure to the endoscopist's face during endoscopy. *Gastroint Endosc*. 89(4), 818-824 doi: 10.1016/j.gie.2018.10.034

References

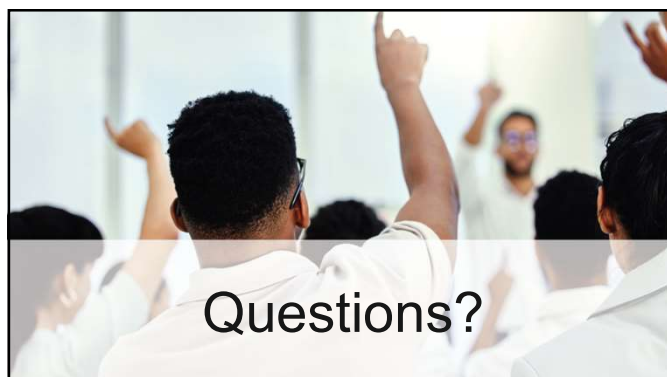
- Kovaleva, J., Peters, F.T., van der Mei, H.C., Degener, J.E. (2013). Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. *Clinical Microbiology Reviews*, 26 (2), 231-254.
- Lewis, D.L., Environmental Research Laboratory, US Environmental Protection Agency, Athens, GA 30613, USA
- Medina, M. and Castillo-Pino, E. (2019) An introduction to the epidemiology and burden of urinary tract infections. *Therapeutic Advances in Urology*, 11, 3-7 DOI 10.1177/1756287219832172
- Occupational Safety and Health Administration Standard 1910.1030 – Bloodborne Pathogens. (d)(2)(viii) Retrieved 9/29/2022 from <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030>
- Ofstead, C. L., Dirlam Langlay, A.M., Mueller, N.J., Tosh, P.K., & Wetzler, H.P. (2013). Re-evaluating endoscopy-associated infection risk estimates and their implications. *American Journal of Infection Control*, 41(8), 734-736.

References

- Ofstead, C.L., Heymann, O.L., Quick, M.R., Eiland, J.E., & Wetzler, H.P. (2018). Residual moisture & waterborne pathogens inside flexible endoscopes. *American Journal of Infection Control*, 46(6), 689-696.
- Ofstead, C.L., Wetzler, H.P., Eiland, J.E., Heymann, O.L., Held, S.B., & Shaw, M.J. (2016). Assessing residual contamination and damage inside flexible endoscopes over time. *American Journal of Infection Control*, 44(12), 1675-1677. DOI: <https://doi.org/10.1016/j.ajic.2016.06.029>
- Ofstead, C.L., Wetzler, H.P., Heymann, O.L., Johnson, E.A., Eiland, J.E., & Shaw, M.J. (2017). Longitudinal assessment of reprocessing. *American Journal of Infection Control*, 45(2), e26-e33. DOI: <https://doi.org/10.1016/j.ajic.2016.10.017>
- Ofstead, C.L., Wetzler, H.P., Snyder, A.K., & Horton, R.A. (2010). Endoscope reprocessing methods. *Gastroenterology Nursing*, 33(4), 304-311. DOI: 10.1097/SGA.0b013e3181e9431a
- Parente, D.M. (2007). Could biopsy valves be a source of potential flexible endoscope contamination? *Infection Control Today*, 11 (6)

References

- Perumpail, R.B., Marya, N.B., McGinty, B.L., & Muthasamy, V.R. (2019). Endoscope reprocessing: Comparison of drying effectiveness and microbial levels with an automated drying and storage cabinet with forced filtered air and a standard storage cabinet. *American Journal of Infection Control*, 000, 1-7
- Simmering, J.E., Tang, F., Cavanaugh, J.E., Polgreen, L.A., & Polgreen, P.M. (2017) The increase in hospitalizations for urinary tract infections and the associated costs in the United States, 1998-2011. *Open Forum Infectious Diseases*, 4(1), ofw281. doi: 10.1093/ofid/ofw281
- Society for Gastroenterology Nurses and Associates (2018) Standards of Infection Prevention in Reprocessing Flexible Endoscopes. SGNA Chicago, IL
- Suliburk, J.W., et al. (2019). Analysis of Human Performance Deficiencies Associated With Surgical Adverse Events. *JAMA*, 2(7):e198067. doi:10.1001/jamanetworkopen.2019.8067
- Vertes, A., Hitchins, V., & Phillips, K.S. (2012). Analytical Challenges of Microbial Biofilms on Medical Devices. *Analytical Chemistry*, 84, 3858-3866. dx.doi.org/10.1021/ac2029997j
- Wang, P., Xu, T., Ngamruengphong, S., Makary, M.A., Kallou, A., & Hutfless, S. (2018). Rates of infection after colonoscopy and oesophagoscopy in ambulatory surgery centres in the USA. *Gut*, 67, 1626-1636



Questions?

