A scanning electron micrograph (SEM) showing a dense cluster of bacteria. The bacteria are primarily rod-shaped with a textured, almost crystalline surface. Some are shorter and more rounded, while others are longer and more cylindrical. They are interconnected by thin, brownish filaments. The background is dark, making the light-colored bacteria stand out.

Cheri Ackert-Burr
RN, MSN, CNOR, AGTS

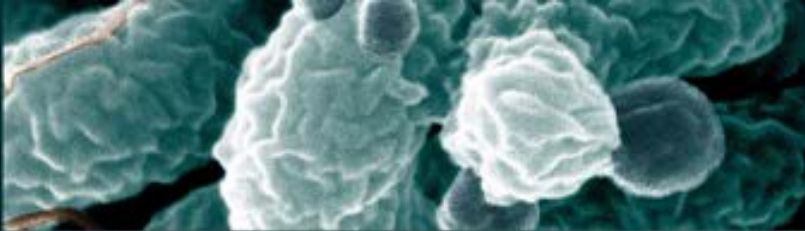
bacteria

Infection Control in
Endoscopy: Using
Guidelines to
Achieve Excellence



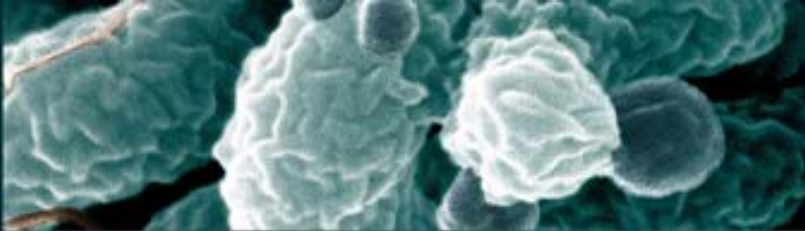
Disclosures

1. Successful completion: Participants must complete the entire program and submit required documentation.
2. Conflict of interest: Planners disclose no conflict; the speaker discloses employment with Medivators, thereby declaring a conflict of interest
3. Commercial company support: Fees are underwritten by education funding provided by Medivators.
4. Alternative/Complementary therapy: None



Objectives

- Review Guidelines related to Infection Prevention
- Identify areas where infection control in endoscopy can be improved
- Discuss chemistries used in the cleaning and high level disinfection
- Present alternative solutions for preventing infection transmission related to reprocessing endoscopes and accessories



Guidelines

- Why they are important
 - Provides evidence based practice to support the rationale for the actions
 - Provide a system to have standardized care delivered to patients
 - Developed and researched by key opinion leaders, physicians, nurses, and professional organization officers

Society Guidelines Revised



2015



2016



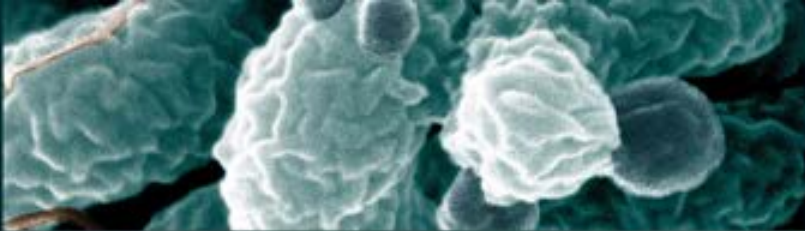
2015



2007



2016



Regulatory Guidelines



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health



**Occupational Safety
and Health Administration**



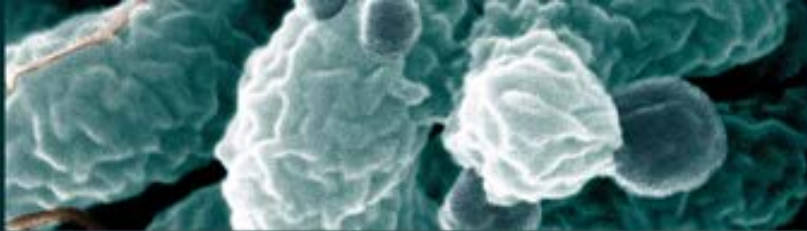
**Department of
Veterans Affairs**

-
- State Mandates
- Local Mandates



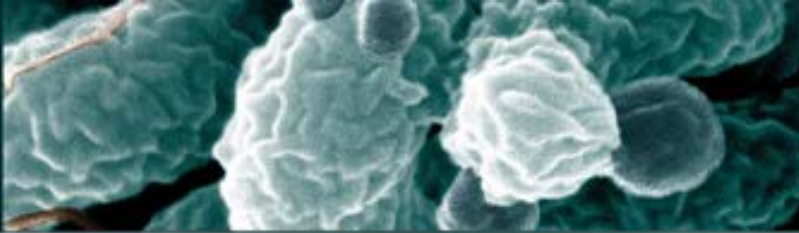
Guidelines





Departments Using Guidelines

ANSI/AAMI	AORN	SGNA
Sterile Processing Department	Operating Room	Endoscopy Suite
Operating Room	Day Surgery	Endoscopy Clinic
Day Surgery	Sterile Processing Department	Physician's Office
Infection Control Nurse	Infection Control Nurse	Infection Control Nurse



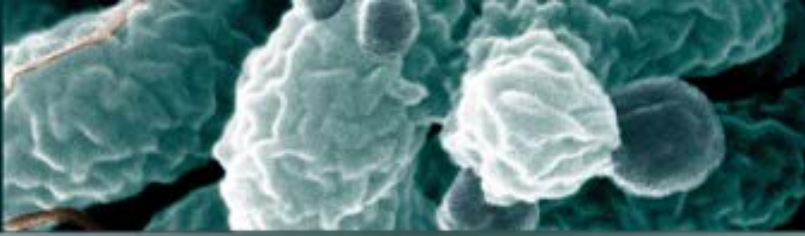
Issues With Professional Guidelines

- No consensus
- Auditors may use more stringent ANSI/AAMI
- Specificity in the guidelines
- Understanding how to use guidelines
- Confusion of when to use manufacturers' Instructions for Use (IFU) or follow guidelines
- What to do when guidelines don't fit

Guidelines

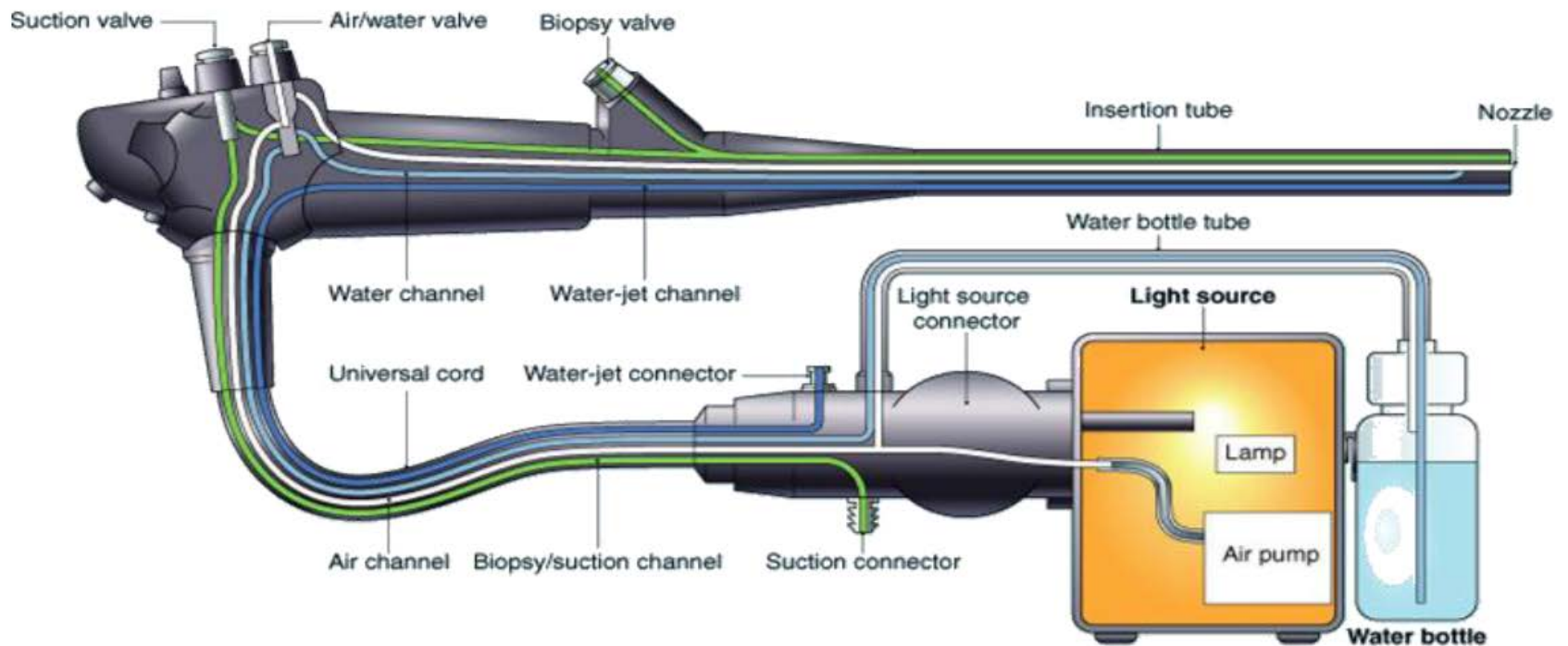
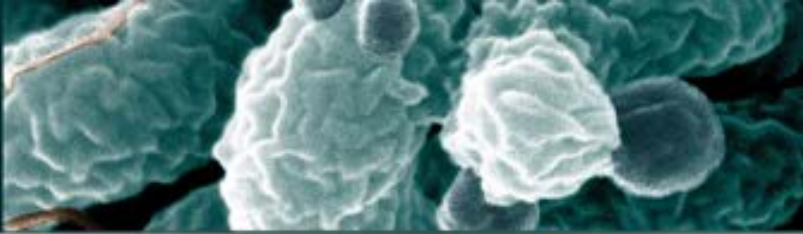
**One size
does not fit all**

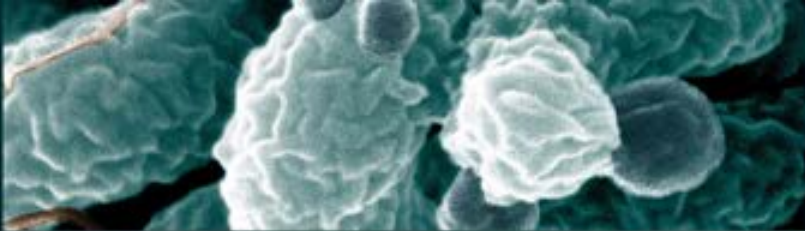




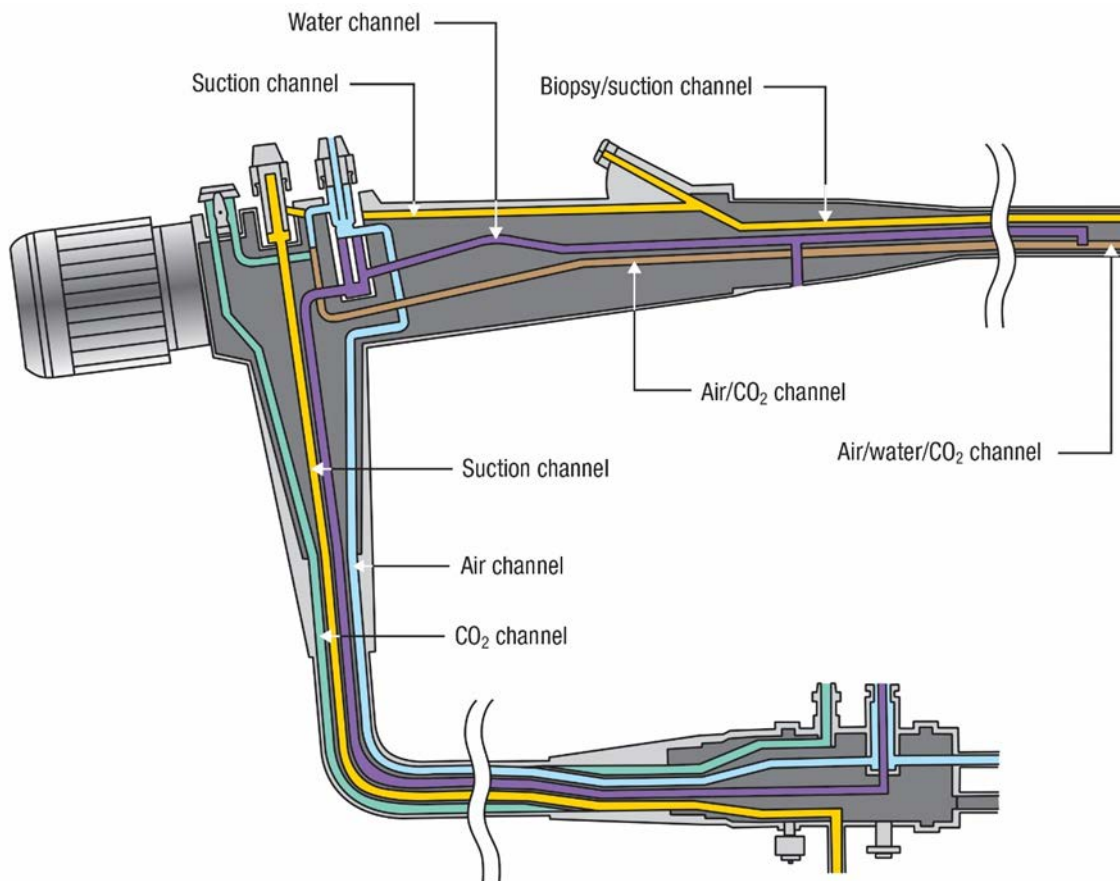
Micro-organisms

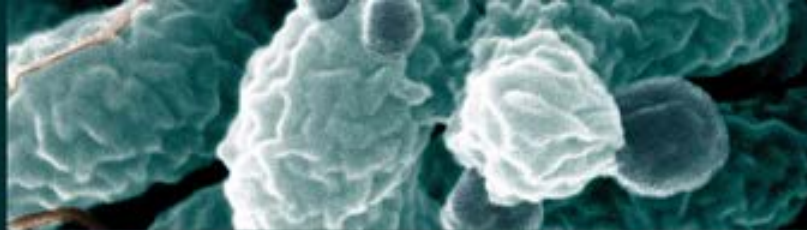
Sources of Contamination





Mechanically Complex

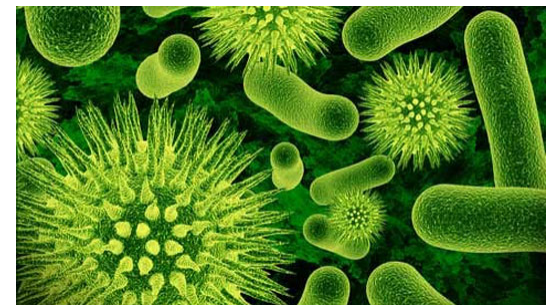
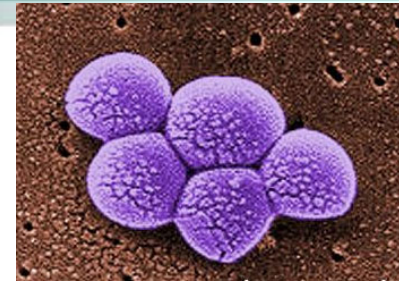
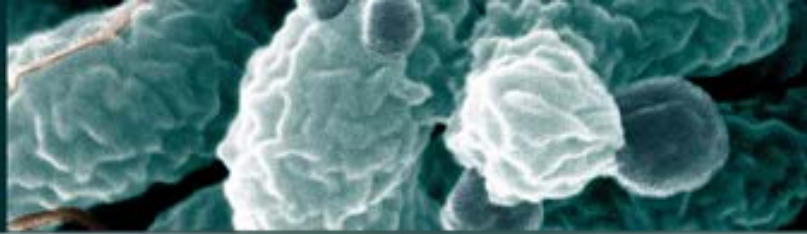




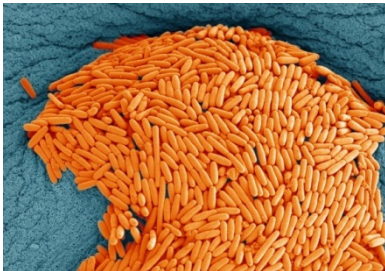
Pathogenic Disease producing

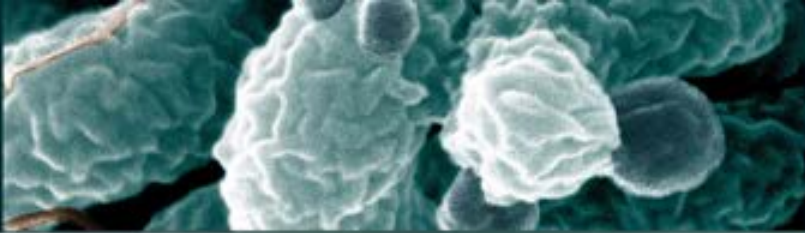
- Immuno-compromised
 - Chemo therapy
 - Transplant patients
 - Chronic disease process
- Elderly
 - Multi system involvement
- Very young
 - Limited antibodies
- Number of organisms
 - Precleaning at point of use
 - Manual or automated cleaning bioburden reduction
- Nonpathogenic can turn pathogenic with the right conditions

Multidrug Resistant Organisms



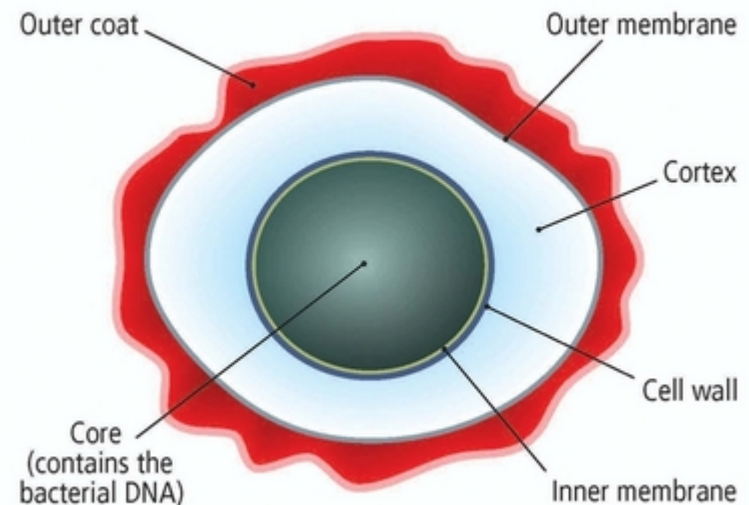
- MRSA
 - Methicillin resistant *staphylococcus aureus*
- VRE
 - Vancomycin resistant *enterococcus*
- CRE
 - Carbapenem-resistant *Enterobacteriaceae*
- *Clostridium Difficile*

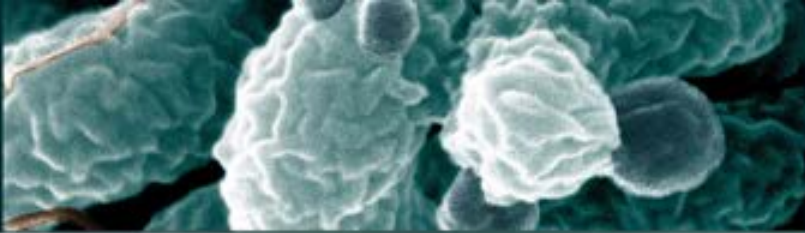




Endospores

- Resistant, dormant, survival form of bacteria
- Spore producing organisms
 - Bacillus anthracis
 - Anthrax
 - Clostridium tetani
 - Tetanus
 - Clostridium botulinum
 - Food poisoning
 - Clostridium difficile
 - C diff

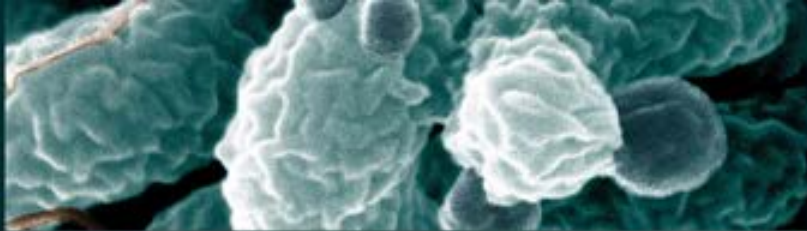




Biofilm

- Micro-organisms surrounded by the slime they produce
- Exists wherever surfaces contact water
- Bacteria live in biofilm communities
- Interferes with disinfection
- All surfaces easily colonized
- Difficult to remove
- Transient vs adherence





Biofilm Timeline

Steps in Biofilm formation

REVERSIBLE
ADSORPTION
OF BACTERIA
(sec.)

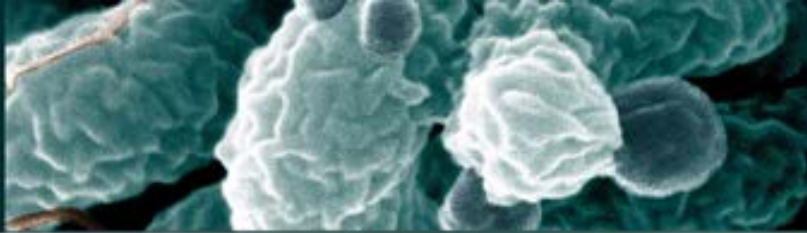
IRREVERSIBLE
ATTACHMENT
OF BACTERIA
(sec.-min.)

GROWTH &
DIVISION
OF
BACTERIA
(hrs.-days)

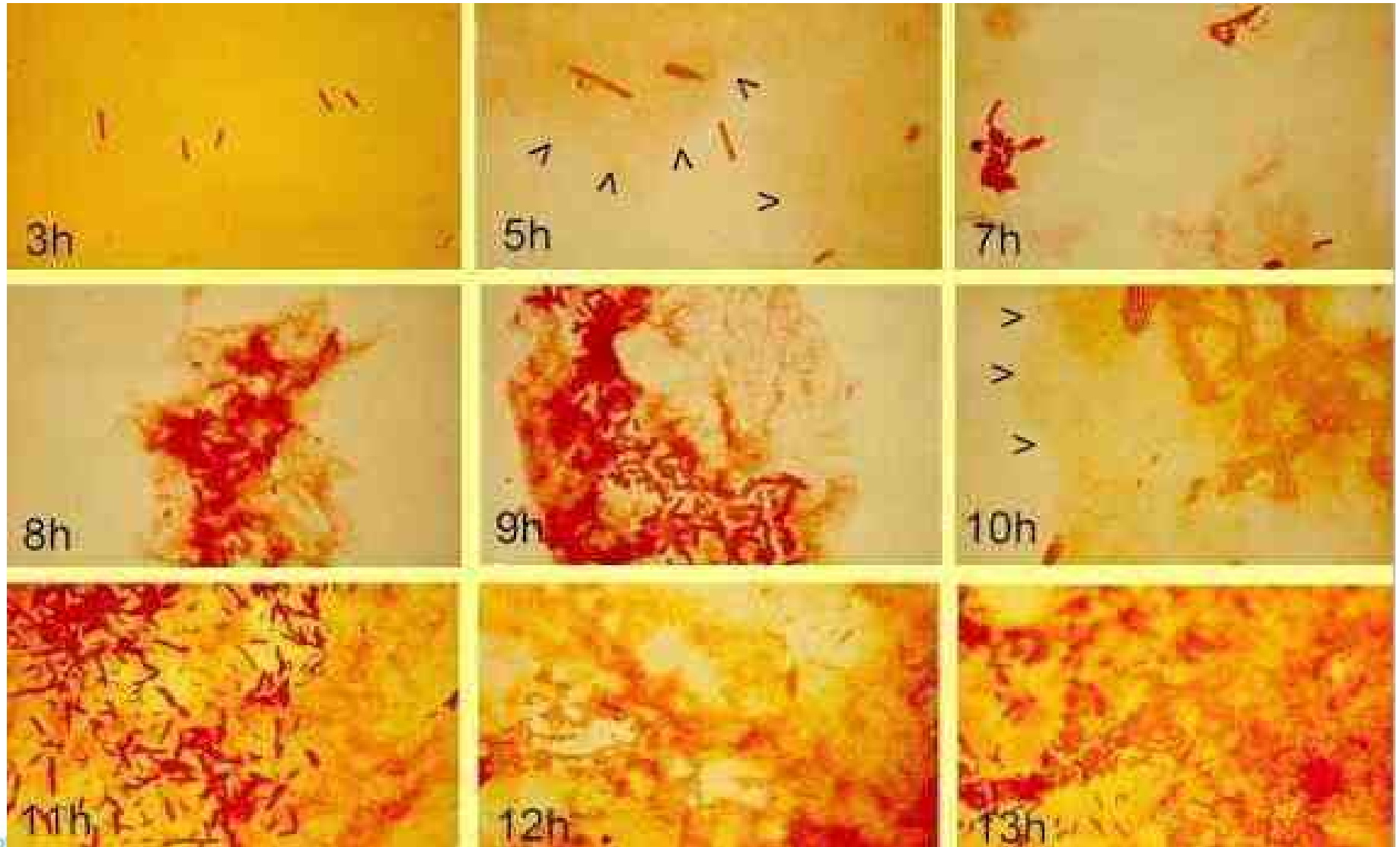
EXOPOLYMER
PRODUCTION
& BIOFILM
FORMATION
(hrs.-days)

ATTACHMENT
OF OTHER
ORGANISMS TO
BIOFILM
(days-months)





Biofilm Growth

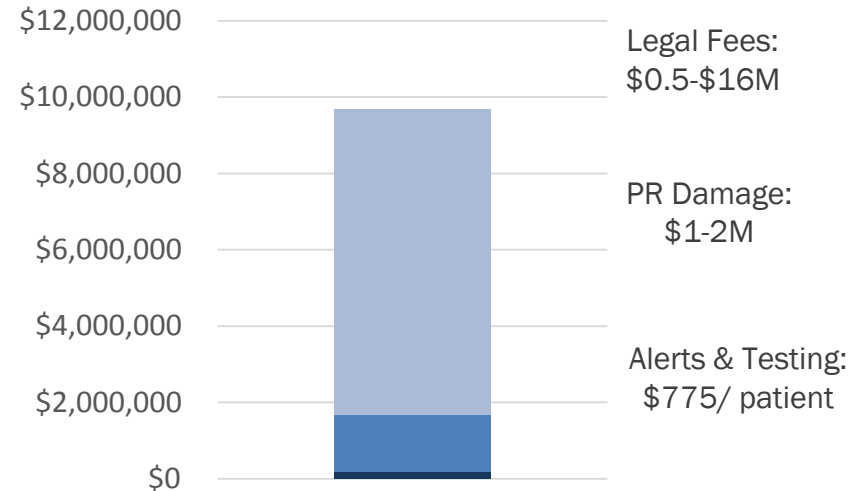


Threat & Implications of Scope Contamination

Top 10 Health Technology Hazards by the ECRI Institute included endoscope reprocessing for the past **7 years**:^{1,2}

- 2010 ○ #1: Cross-contamination of endoscopes
- 2011 ○ #3: Cross-contamination of endoscopes
- 2012 ○ #4: Cross-contamination from flex. endoscopes
- 2013 ○ #8: Inadequate reprocessing of endoscopes and surgical instruments
- 2014 ○ #6: Inadequate reprocessing of endoscopic devices and surgical instruments
- 2015 ○ #8: Inadequate reprocessing of endoscopes and surgical instruments
- 2016 ○ #1: Inadequate cleaning of flexible endoscopes before disinfection can spread deadly pathogens

Estimated Hospital Financial Consequence of Incident^{1,2}

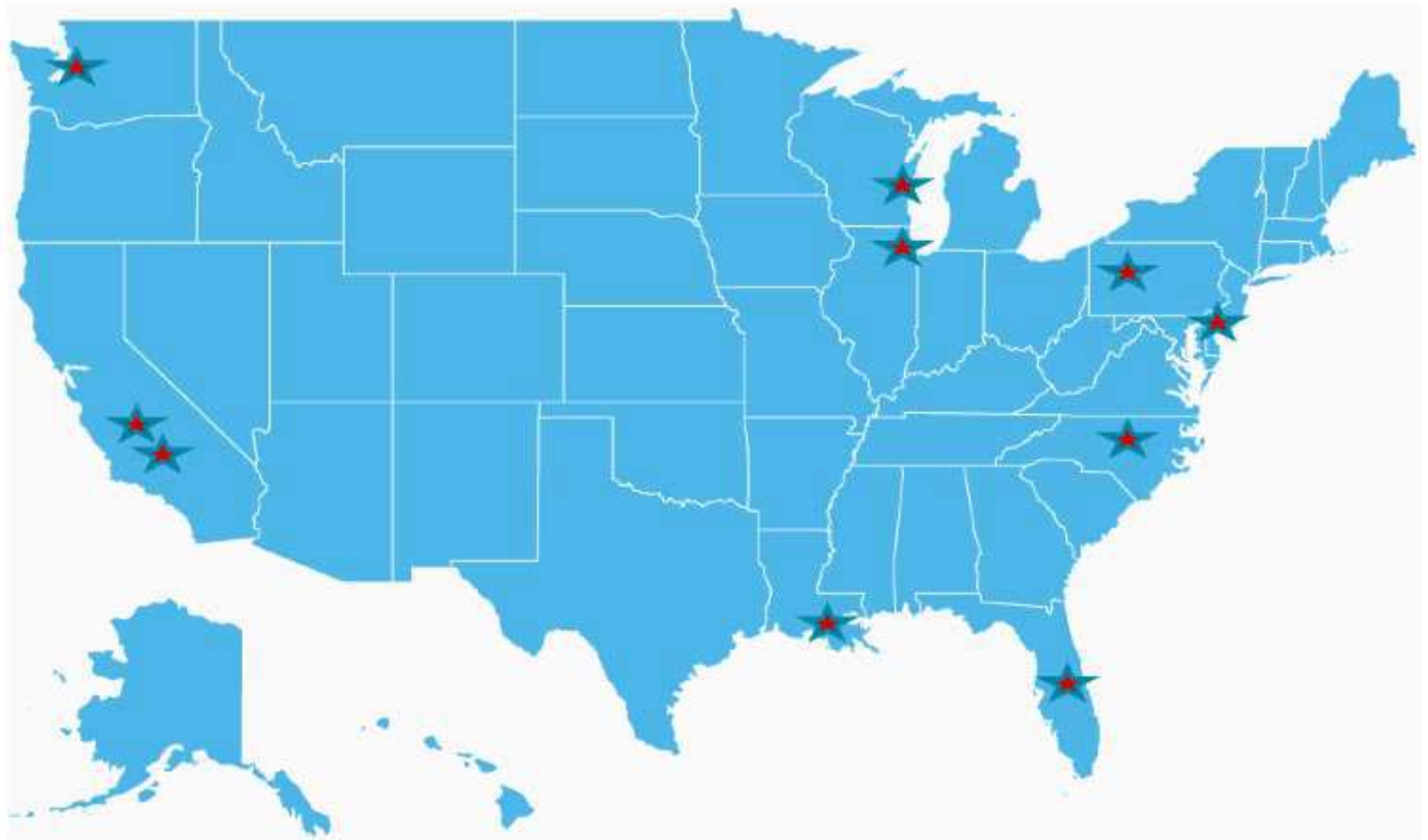


Total estimated cost per incident: \$2M-20M

FDA and CDC acknowledge³:
“Flexible endoscopes are fundamentally difficult to clean and disinfect or sterilize”

1: “Excellence in Scope Reprocessing” session at 2016 SGNA Conference by Laura H. Schneider, RN CGRN CASC of AMSURG Corporation 2: “Is That Scope Really Clean?” session at 2016 SGNA Conference by Barbara Zuccala, MSN RN CGRN of The Valley Hospital 3: “Preventing Cross-Contamination in Endoscope Processing: FDA Safety Communication” FDA 2009

Reported Duodenoscope-Related MDRO Outbreaks 2013-2015



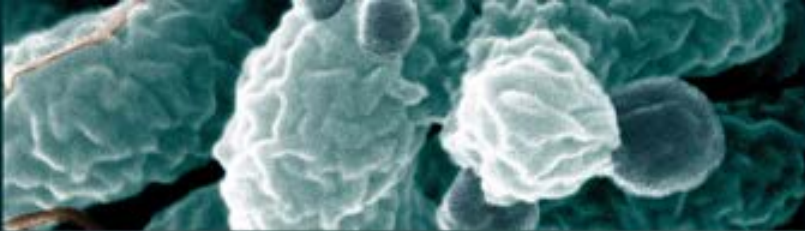
Superbug found at suburban hospital

Lutheran General, health officials taking steps to prevent spread of CRE



Superbug linked to 2 deaths at
UCLA hospital; 179 potentially
exposed



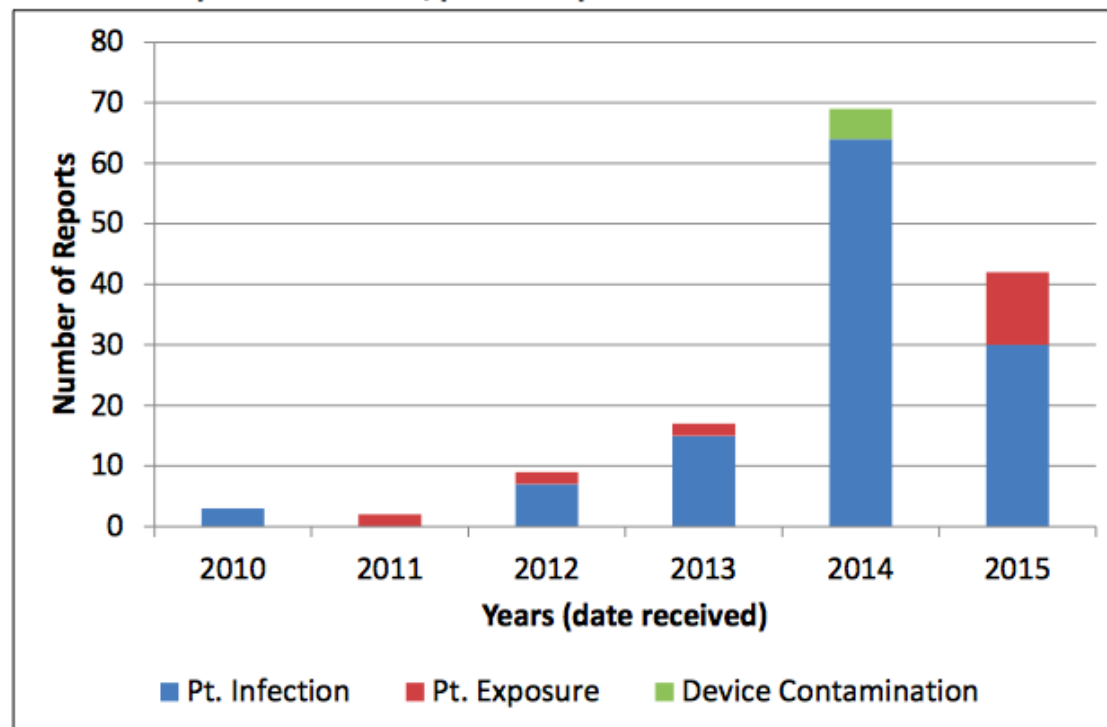


Medical Device Adverse Event Reports (MDR)

Increase in Duodenoscope Infection Reports 2010-2015

MDR Results

Number of MDR reports^{1,2,3} received for duodenoscopes associated with patient infection, patient exposure or device contamination



1: Each MDR may report events associated with none, one or more patients

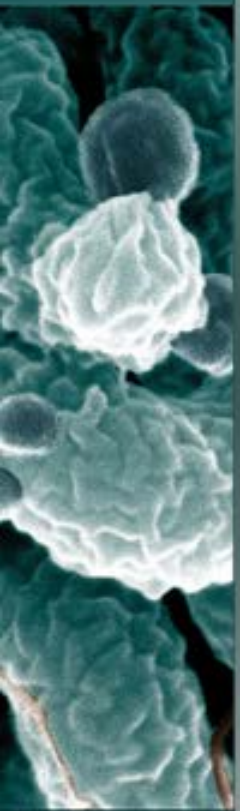
2: 2015 year only includes data received as of February 17, 2015.

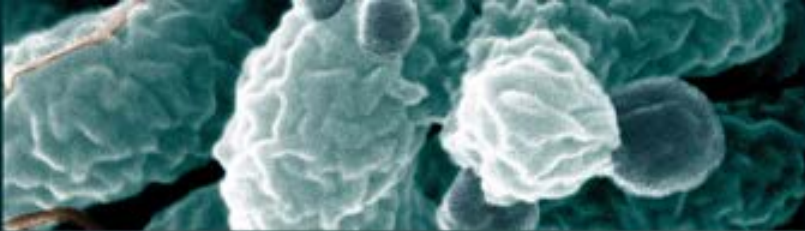
3: Reports received prior to 2010 (n=4) not shown in this figure

Donayere JD, FDA, Mat 2015

Flexible Endoscope Reprocessing Concerns

- Mechanically complex devices
- Frequent technology or mechanical updates
- Increased technical difficulty of procedures
- Minimally invasive procedures are increasing
- Longer procedures means more difficulty during cleaning procedures
- Many models of scopes require many IFUs
- Skills acquisition for reprocessing takes time and ongoing education
- Ongoing oversight is critical to maintaining best reprocessing practices





FDA Alert

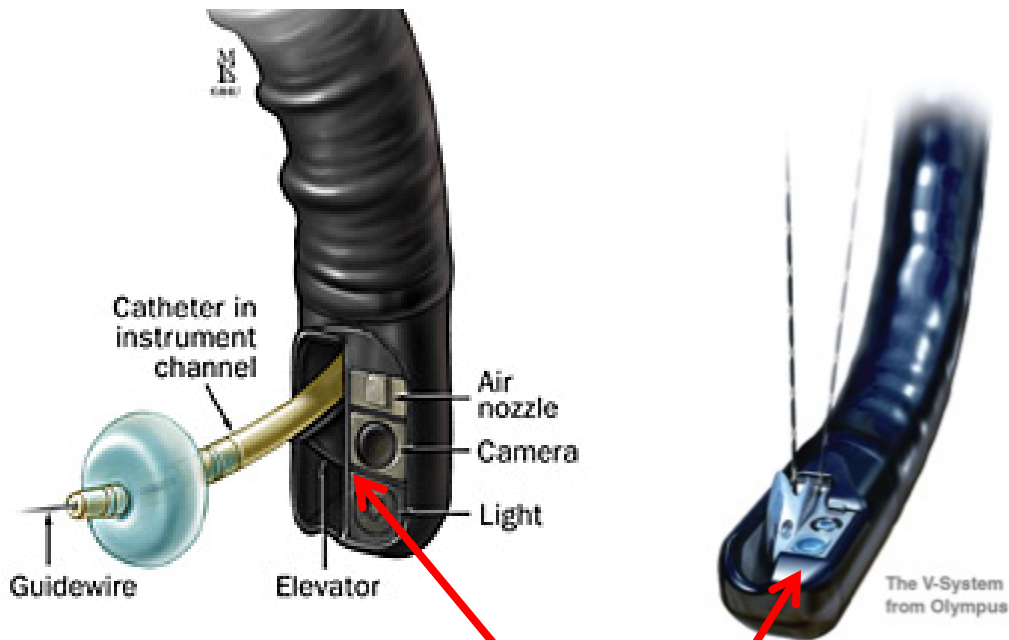
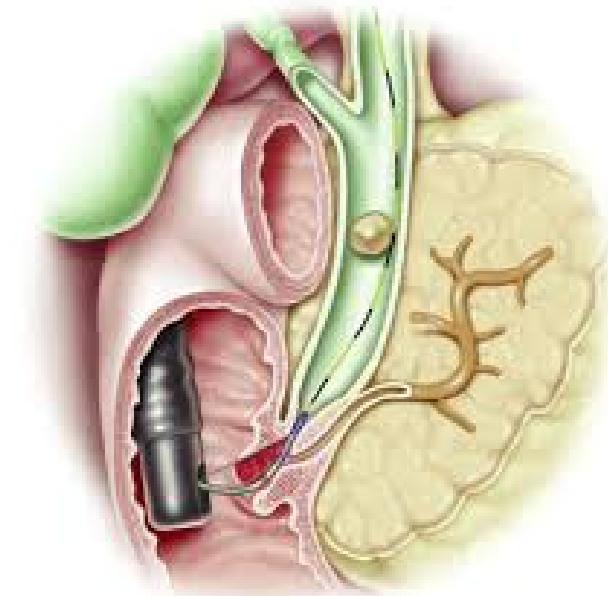


Photo courtesy of Olympus America Inc.



Why it needs to be side viewing with elevator lifts



Problem child for reprocessing

- **Outlined supplemental measures for facilities and staff that reprocess duodenoscopes to consider:**
 - Microbiological culturing
 - Ethylene oxide sterilization
 - Use of a liquid chemical sterilant processing system
 - Repeat high-level disinfection
- **FDA recommended health care facilities performing ERCP evaluate whether they have the expertise, training and resources to implement one or more of these options**

Preventing Exposures and Transmissions





Reprocessing Steps

Point of Use Precleaning

- Immediately upon withdrawal
- Water/air/detergent solution

Leak Test

- Dry – manual or automated
- Wet – manual or automated

Manual Cleaning

- Brushing/flushing
- Rinsing

Visualization

- Magnification 10X
- Newest called out step



Reprocessing Steps

High Level Disinfection

- Manual
- Automated

Rinsing

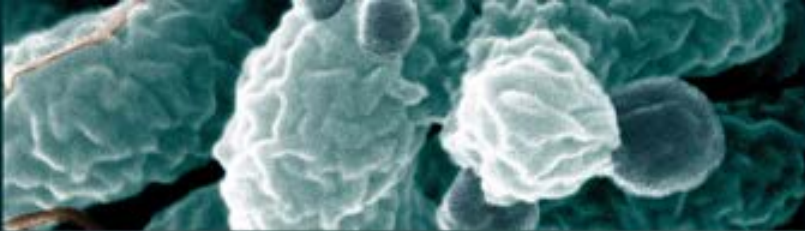
- Manual – Sterile water, Reverse Osmosis
- Automated – Hepa Filtered

Forced air Alcohol Purge

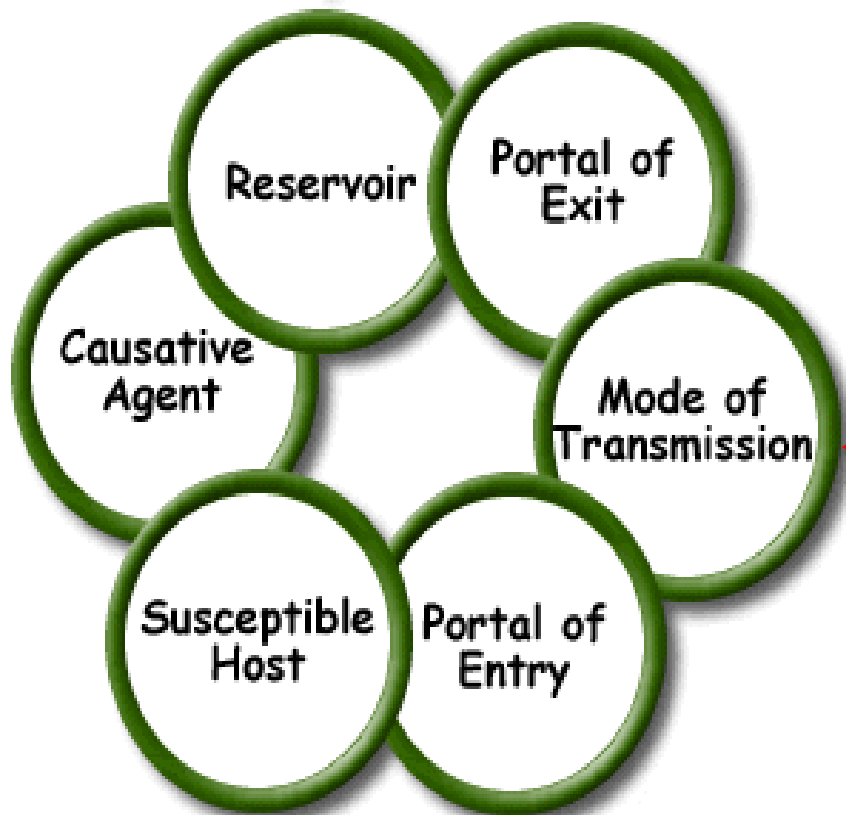
- Low pressure instrument air– not syringe air
- 70-90% isopropyl alcohol

Storage

- Vertical – hanging
- Horizontal –drying/storage cabinet



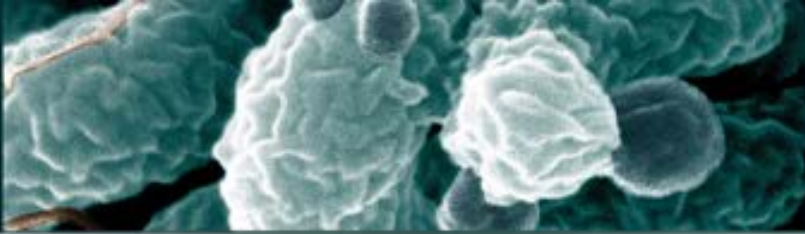
Chain of Infection



The Bug Stops Here

- Bedside precleaning
- Contained transportation
- Cleaning and decontamination
- Drying
- Storage
- Maintenance

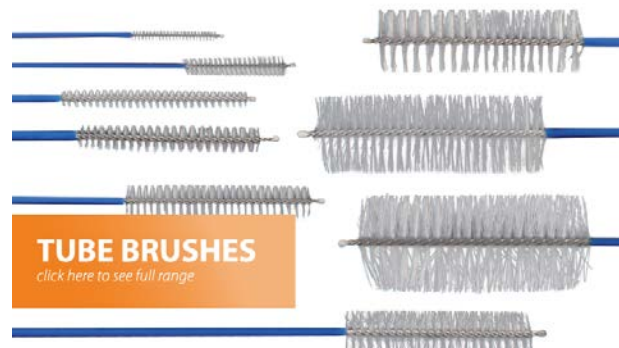
Sources of Contamination



MISSED SPOTS WHEN HAND-WASHING



- MOST FREQUENTLY MISSED
- LESS FREQUENTLY MISSED
- NOT MISSED

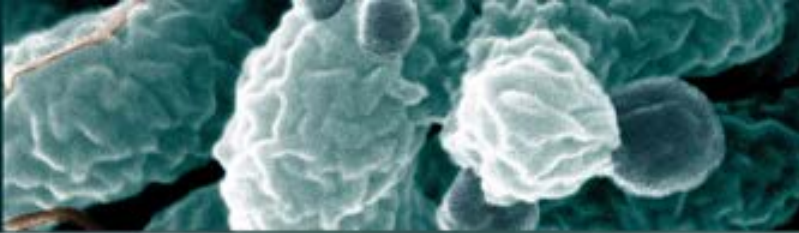


TUBE BRUSHES

[click here to see full range](#)



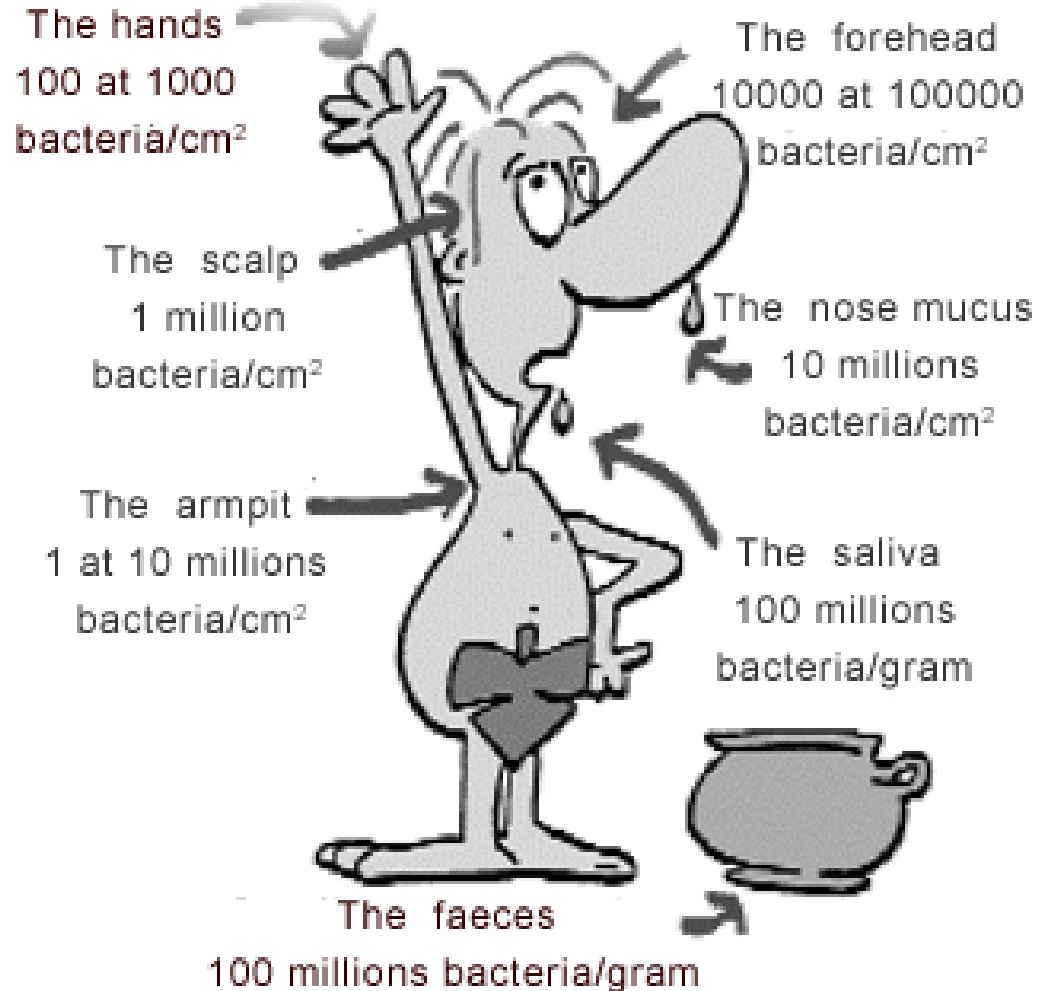
Microorganisms on our Person



1 sq in



1 sq cm



**4-5 pounds of
bacterial cells
in the body**

**1 gram = 1/5
teaspoon or
.035 oz**



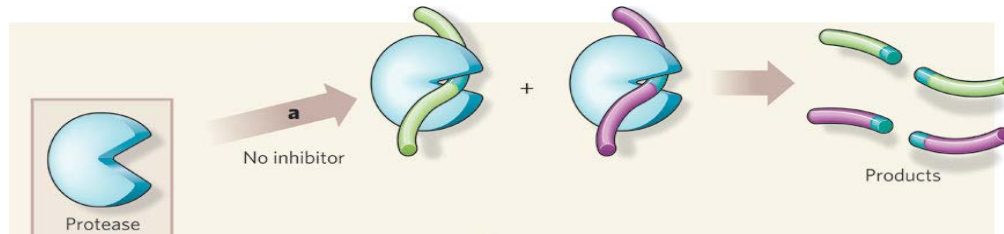
Combating Infection Thru Chemistry

- Detergents
 - Enzymatics
 - Non enzymatic - biofilm detaching agents
- Disinfectants
 - Glutaraldehyde
 - Ortho-phthalaldehyde (OPA)
 - Peracetic acid
 - Hydrogen peroxide
- 70% Ethyl or isopropyl alcohol

Detergents

Enzymatics

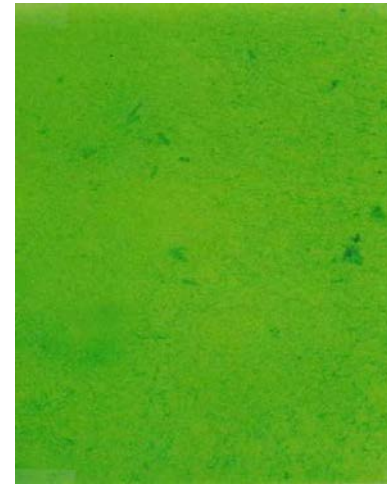
- Reduce cohesive forces and act like scissors to break up soil



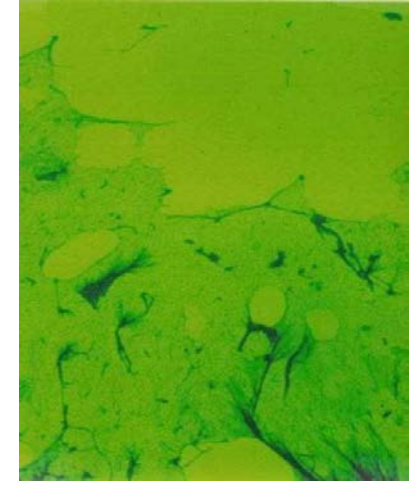
- Substrate specific – only breakdown what they are attracted to
- Types of enzymes (substrates)
 - Protease – proteins (blood, mucus, body fluids)
 - Amylase - carbohydrates
 - Lipase - fats
- Each cleaning cycle uses up the enzymes for each scope – **get clean detergent solution for each scope, Do Not Reuse**

Biofilm Detaching Agent Detergent

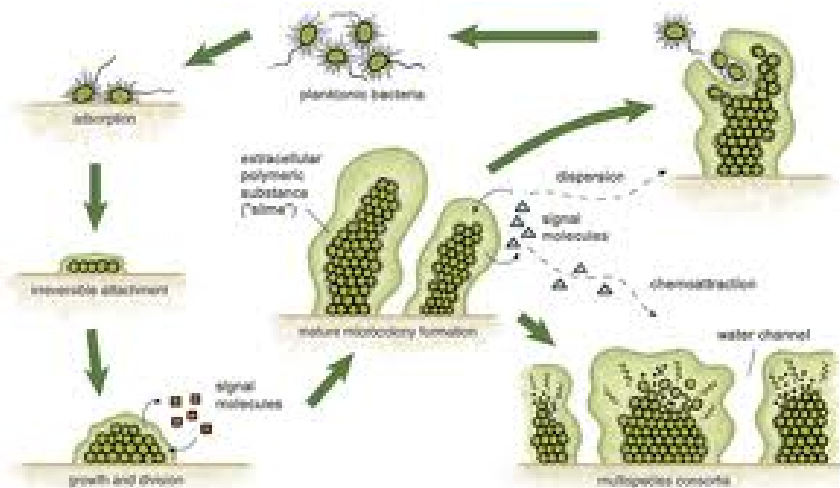
- Biofilm can form wherever a surface is exposed to a fluid pathway
- Enzymes are unable to react with biofilm EPS matrix

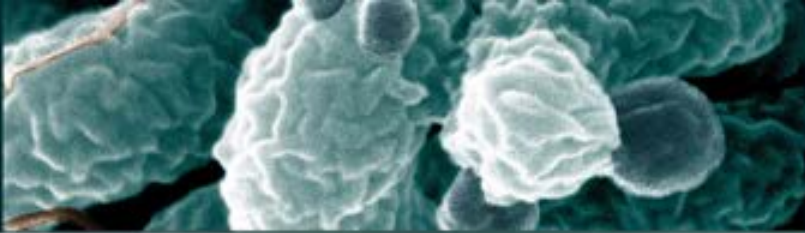


6 day growth of a *P. Aeruginosa* biofilm



Biofilm treated with a bio-film detaching detergent





Detergent Types

- Enzymatic detergents
 - Act by reducing cohesive force within soil itself
 - Digests the outer shell of biofilm
 - Formulations consist of one or more substrate specific enzymes

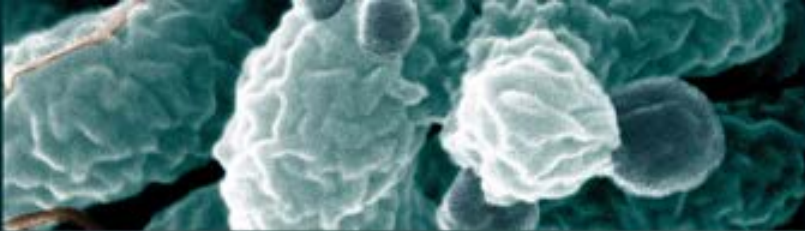
- Non-enzymatic detergents
 - Acts by reducing chemical bonding between soil and endoscope surface
 - Penetrates through biofilm to reach the surface of the endoscope





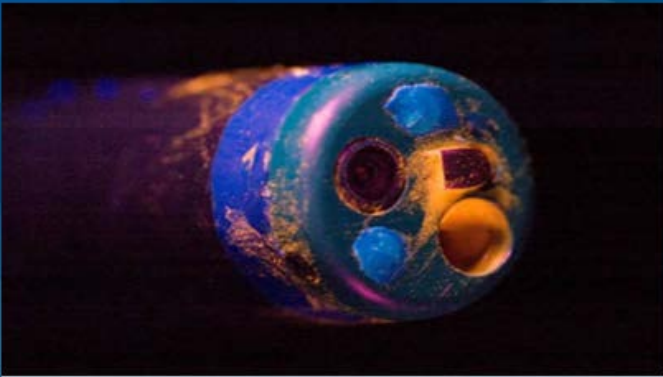
Detergents Recipe

- Clean solution for each scope – Do Not Reuse
- Correct concentration – per IFU (instructions for use)
- Correct contact time – each detergent is different
- Correct temperature – some detergents require heated water

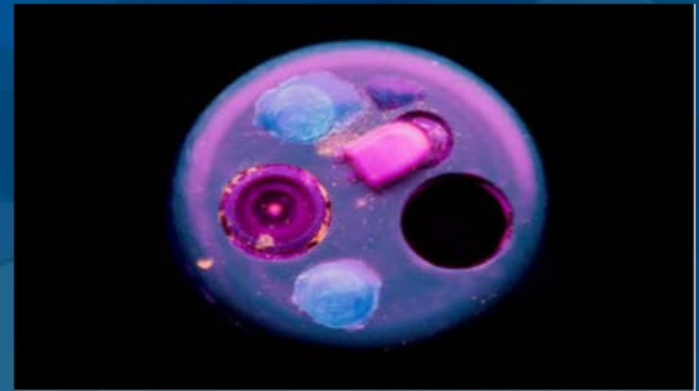


Biofilm Revealed

Photographic Documentation of Endoscopic Biofilm



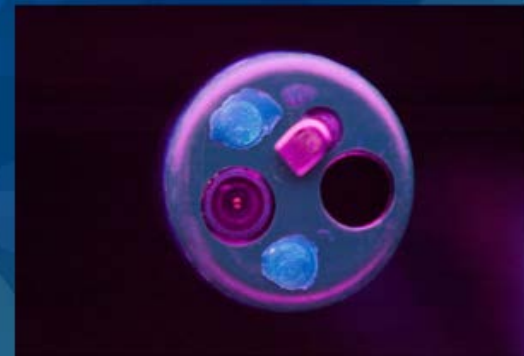
Scope Tip after Manual Cleaning



Distal Tip after Cidex and Alcohol



Distal Tip after Peracetic Acid



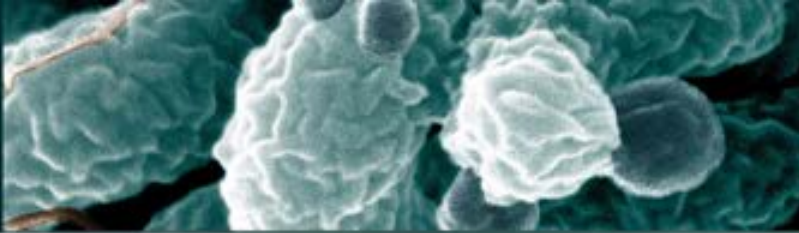
Sterilization	High Level Disinfection	Intermediate Disinfection	Low Level Disinfection			
Bacterial Spores Geobacillus stearothermophilus Bacillus subtilis Bacillus atrophaeus Clostridium sporogenes						
Cyst forms of parasites Cryptosporidium oocysts						
Mycobacteria Mycobacterium tuberculosis var. bovis Nontuberculous mycobacteria	Mycobacteria Mycobacterium tuberculosis var. bovis Nontuberculous mycobacteria					
Nonlipid or small viruses Poliovirus Coxsackie virus Rhinovirus	Nonlipid or small viruses Poliovirus Coxsackie virus Rhinovirus	Nonlipid or small viruses Poliovirus Coxsackie virus Rhinovirus				
Fungi Trichophyton spp. Cryptococcus spp. Candida spp.	Fungi Trichophyton spp. Cryptococcus spp. Candida spp.	Fungi Trichophyton spp. Cryptococcus spp. Candida spp.				
Non-cyst forms of parasites	Non-cyst forms of parasites	Non-cyst forms of parasites				
Vegetative bacteria Pseudomonas aeruginosa Staphylococcus aureus Salmonella choleraesuis Enterococci	Vegetative bacteria Pseudomonas aeruginosa Staphylococcus aureus Salmonella choleraesuis Enterococci	Vegetative bacteria Pseudomonas aeruginosa Staphylococcus aureus Salmonella choleraesuis Enterococci	Vegetative bacteria Pseudomonas aeruginosa Staphylococcus aureus Salmonella choleraesuis Enterococci			
Lipid or medium-sized viruses Herpes simplex virus Cytomegalovirus Respiratory syncytial virus Hepatitis B virus Hepatitis C virus Human immunodeficiency virus	Lipid or medium-sized viruses Herpes simplex virus Cytomegalovirus Respiratory syncytial virus Hepatitis B virus Hepatitis C virus Human immunodeficiency virus	Lipid or medium-sized viruses Herpes simplex virus Cytomegalovirus Respiratory syncytial virus Hepatitis B virus Hepatitis C virus Human immunodeficiency virus	Lipid or medium-sized viruses Herpes simplex virus Cytomegalovirus Respiratory syncytial virus Hepatitis B virus Hepatitis C virus Human immunodeficiency virus			

Prions, the causative agents of transmissible spongiform encephalopathies, present a unique resistance challenge to germicidal chemicals. Prions have been shown to have unusually high resistance to heat and chemicals, in some cases demonstrating greater resistance than bacterial spores. In suspected or confirmed cases, special consideration should be given to prion decontamination. See AORN recommendations regarding processing of prions



High Level Disinfectants

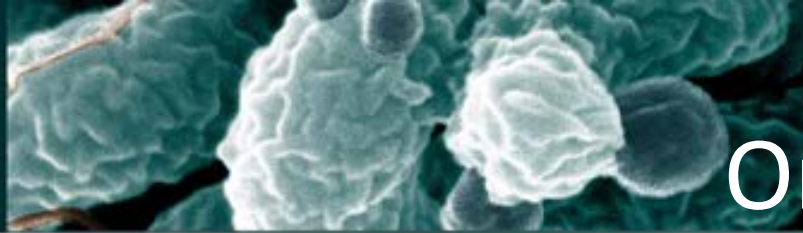
- Glutaraldehyde
 - Reusable
- Ortho-phthalaldehyde (OPA)
 - Reusable
- Peracetic acid (PAA)
 - Single shot
 - Reusable



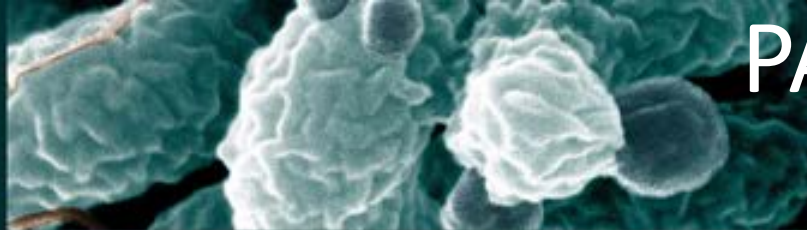
Glutaraldehyde

Advantages	Disadvantages	Concentration	Contact time Conditions
<ul style="list-style-type: none">• Lots of studies for efficacy available• Relatively inexpensive• Excellent compatibility	<ul style="list-style-type: none">• Respiratory irritant• Pungent odor• Slow mycobactericidal activity• Coagulates blood and fixes tissue to surfaces• Allergic contact dermatitis	<ul style="list-style-type: none">• 2.5% glutaraldehyde AER• 1.12% glutaraldehyde and 1.93% phenol	<ul style="list-style-type: none">• 5.0 min @ 35° C (95° F)• 28 days maximum reuse• 20 min @ 25° C (77° F)• 14 days maximum reuse

Ortho-phthalaldehyde

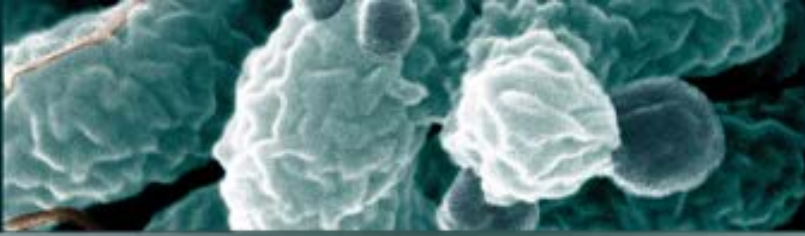


Advantages	Disadvantages	Concentration	Contact Time Conditions
<ul style="list-style-type: none"> • Fast acting • No activation • Odor not significant • Excellent compatibility • Not coagulating blood or fixing tissues to surfaces 	<ul style="list-style-type: none"> • Stains protein gray • More expensive • Eye irritant • Slow sporicidal activity • Bladder cancer patients may have a higher sensitivity to contact 	<ul style="list-style-type: none"> • 5.75% OPA • 0.55% OPA AER • 0.55% OPA AER 	<ul style="list-style-type: none"> • 5 min @ 50°C (122°F) • single use • 12 min @ 20°C (68°F) • 14 days maximum day reuse • 5 min @ 25°C (77°F) • 14 days maximum reuse

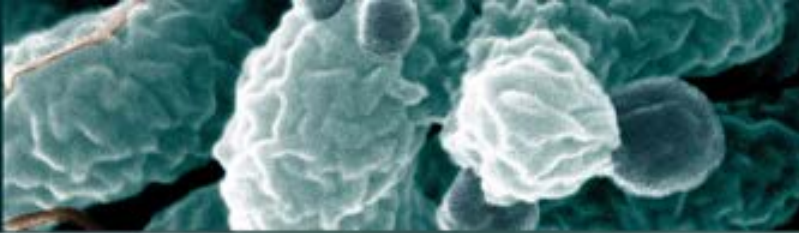


PAA - Peracetic acid & Hydrogen Peroxide

Advantages	Disadvantages	Concentration	Contact Time Conditions
<ul style="list-style-type: none">• No activation• Odor not significant• Irritation not significant	<ul style="list-style-type: none">• Possible compatibility issues (lead, brass, copper, zinc)• Cosmetic changes• Functional damage• Potential eye and skin irritant	<ul style="list-style-type: none">• 0.08% PA and 1.0% hydrogen peroxide• 0.23% PA and 7.35% hydrogen peroxide	<ul style="list-style-type: none">• 25 min @ 20°C (68°F)• 14 day maximum reuse• 15 min @ 20°C (68°F)• 14d

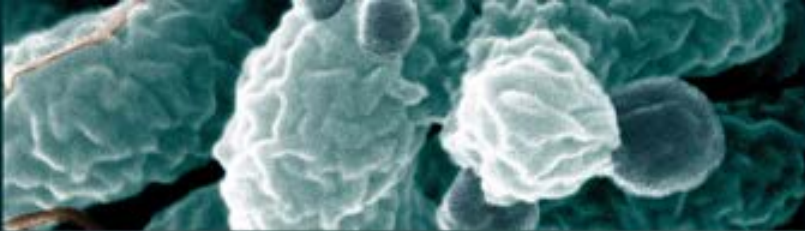


PREVENTION



Where We Can Help

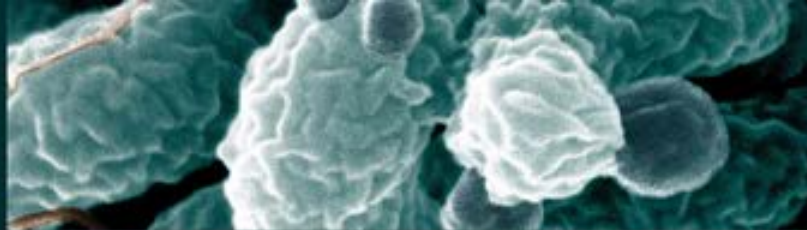
- Precleaning
 - Reducing initial bioburden
- Leak testing
 - Prevents fluid invasion and harboring microorganisms
- Manual cleaning
 - Organic soil removal prepares scope surfaces
- Drying
 - Just as important as cleaning
- Storage
 - Controlled environment
- Transport
 - Scope protected when contaminated and clean
- Traceability
 - Critical touch points



Point of Use

- Pre-Cleaning
 - Wiping down the scope
 - Immediate flushing of solution through the channels
 - Contained transport





Transport

- Must be contained unless immediately next door
- Hazmat symbol
- Contained when going from storage to procedure room

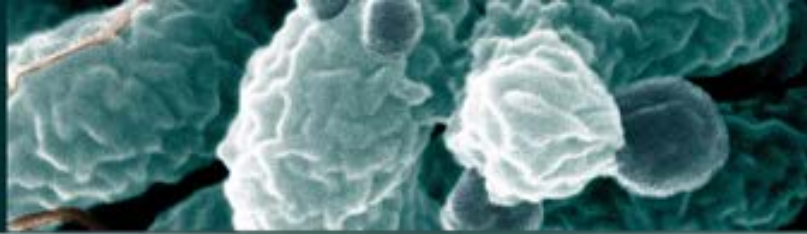


Remember

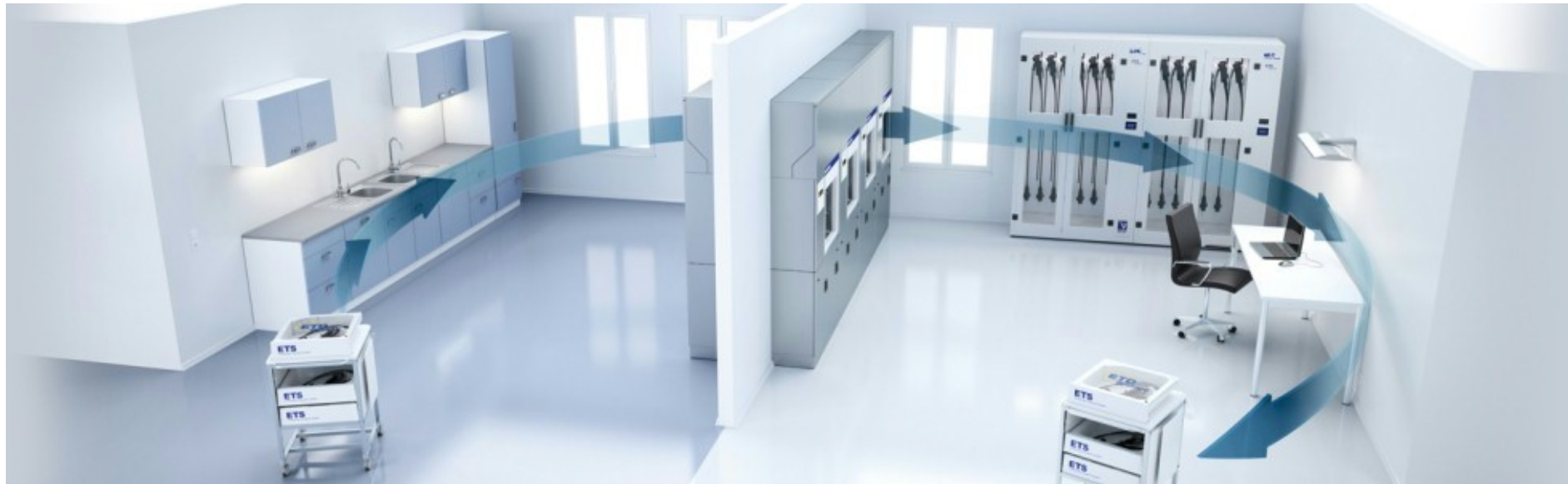


Required for transport

Reprocessing Considerations



- One-way flow



Dirty

Clean

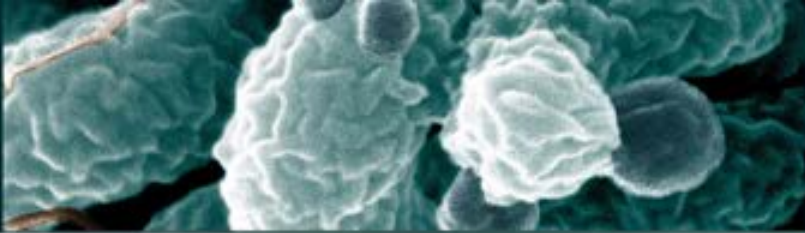
Clean

Dirty



OSHA
Regulatory
Requirement

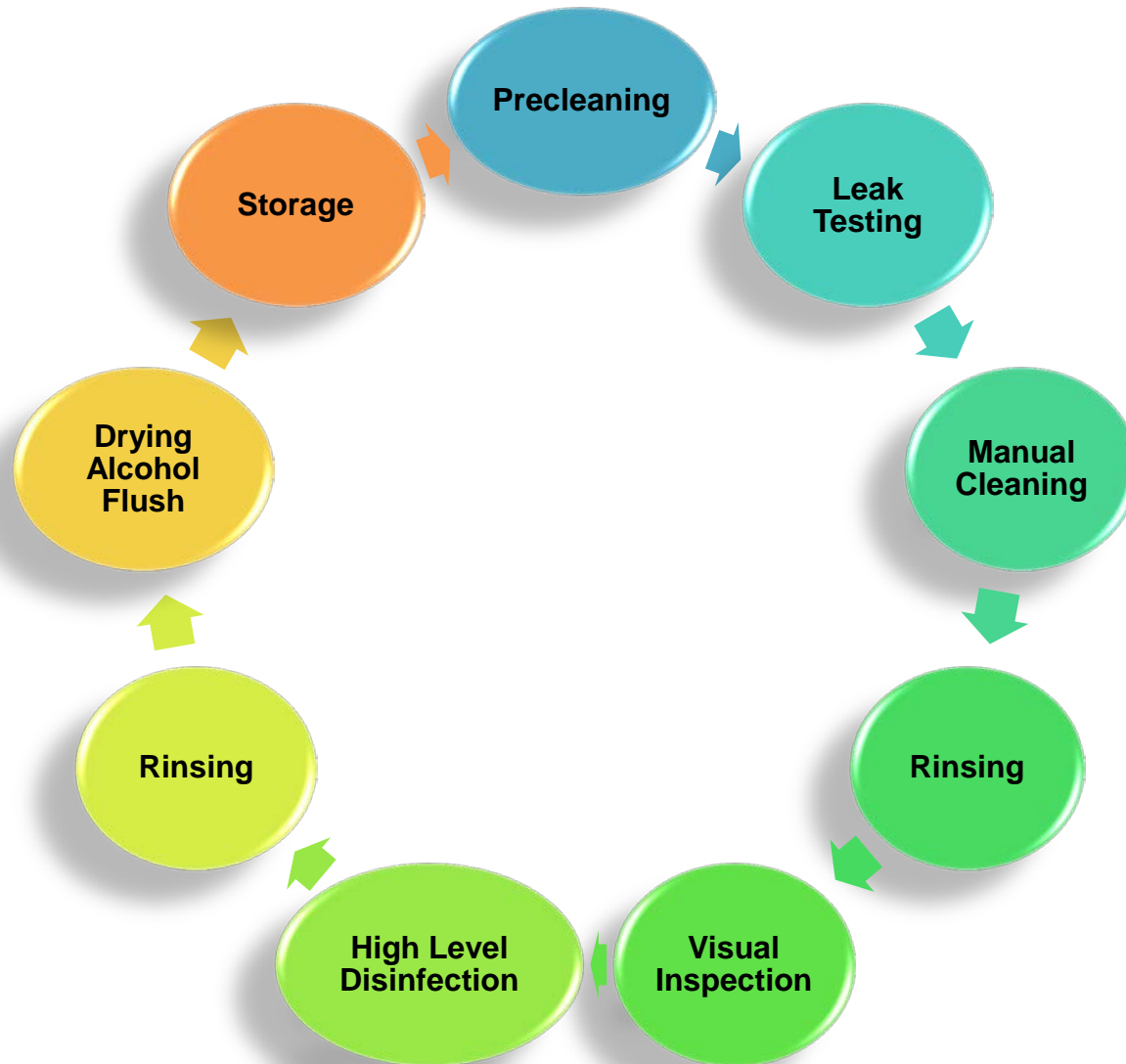
- Transport



Storage

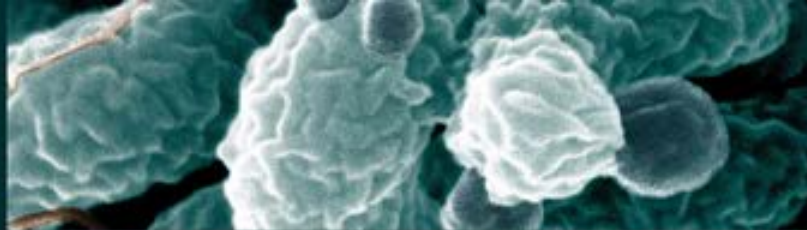


Traceability in Endoscope Reprocessing



Cycle of an Endoscope Traceability





Traceability Requirements

Critical Touch Points

- Procedure Room
- Leak Testing
- Manual / automated cleaning
- Manual / automated high level disinfection
- Drying, alcohol purge
- Storage

Required Identifier Information

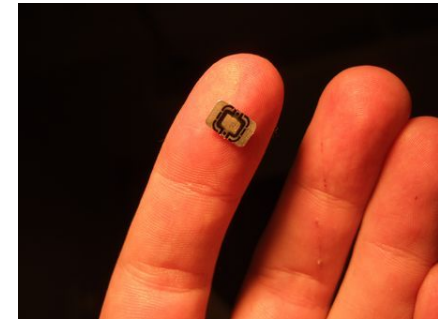
- Patient
- Scope
- Equipment
- Endoscopist
- Times
- Reprocessing personnel at all critical touch points
- Outcomes of all automated systems
- Outcomes of chemistry

Traceability the New Way

Bar Coding Data Matrix Tags



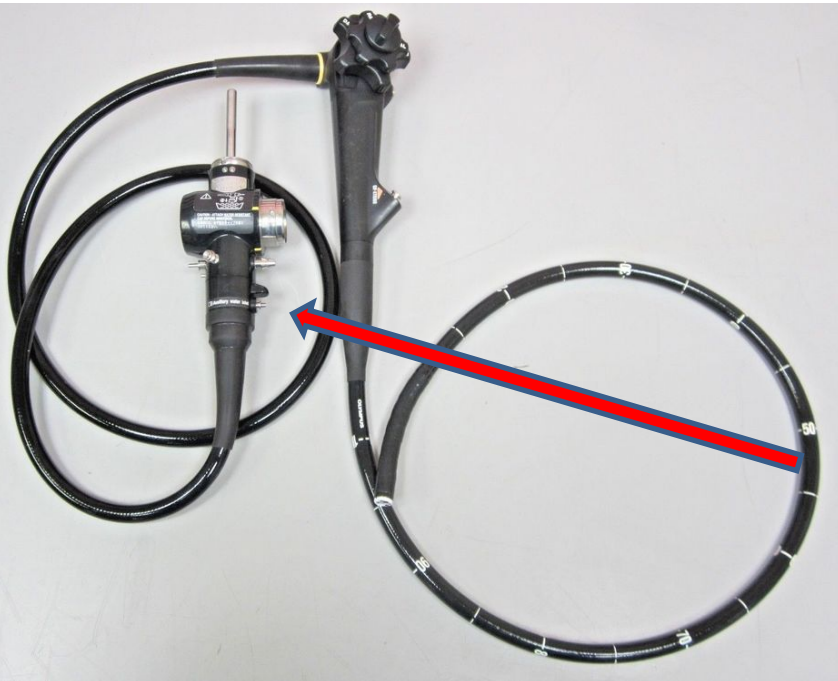
RFID – Radio Frequency Identification



Latest Updates


- **FDA – Mitigating Risk of Cross-Contamination from Valves and Accessories Use for Irrigation Through Flexible Gastrointestinal Endoscopes 11/29/2016**

1. Highlight cross-contamination risk
2. Clarify terminology for these devices
3. Outline strategies to mitigate the risk of cross-contamination



Forward Water JJet / Auxiliary Water Connector

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM430550.pdf>

- Buttons and valves
 - Reusable buttons and valves should be cleaned and reprocessed with the scope to maintain a unique set for traceability *
 - Alternative solution – disposable buttons and valves 

*AORN, 2016; SGNA, 2015; AAMI, 2015

 SGNA 2015

Buttons and Valves



**Air / Water
Valves**



**Suction
Valves**



Button and Valve Research

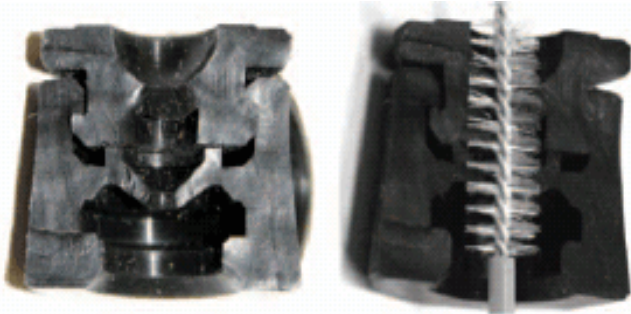


Fig 1.1 — Cross-sectional view of typical biopsy port valve showing nooks and crannies and the inability of cleaning brush bristles to contact all surfaces

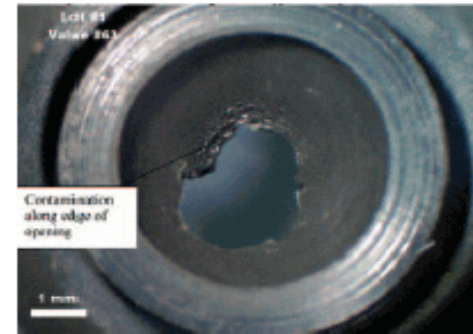


Fig 1.2 — Valve observed during microscopy demonstrates wear and damage after use, manual cleaning, and high-level disinfecting. Note the presence of contamination along edge of the opening.

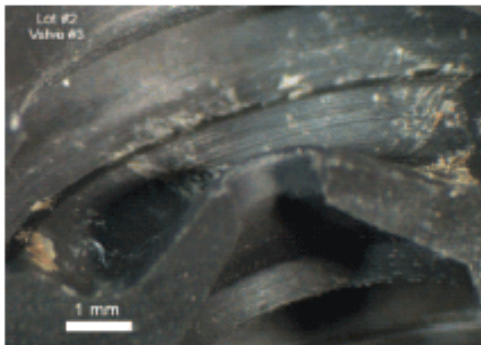


Fig 1.3 — Internal cross section of valve observed at magnification of approximately 10x demonstrates presence of contamination in nooks and crannies of valve.



Fig 1.4 — Valve observed during microscopy at 10x magnification. Note the presence of pinkish droplets on the edge of the valve opening, representing gross contamination.

Auditing Agencies



Accredited by

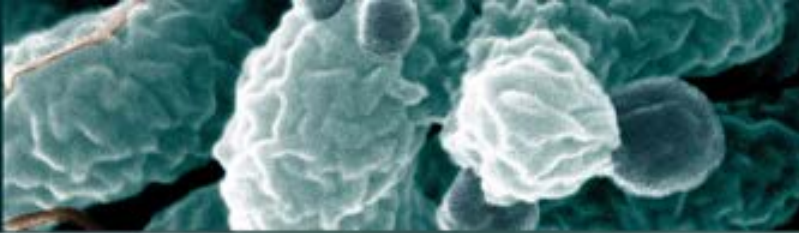


ACCREDITATION ASSOCIATION
for AMBULATORY HEALTH CARE, INC.



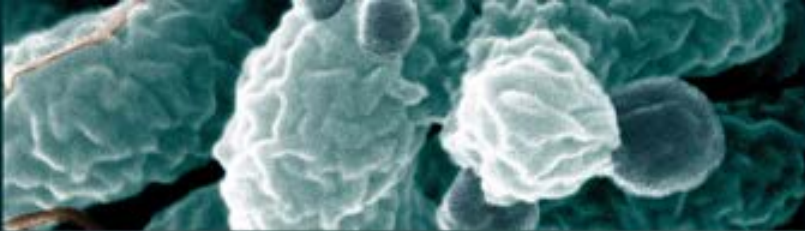
Recommendations Frequently Given by Joint Commission

- No IFU present or followed
- Scopes touching other scopes or walls
- Scopes not protected during transport
- Complete traceability of the scope and accessories
- MRC test results missing
- Leak test results missing
- Education/competency for staff members



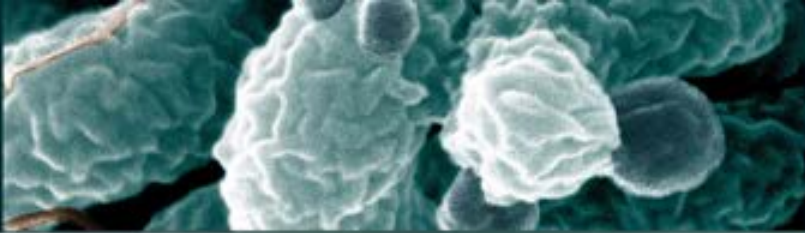
Determining Best Practices

- Review multiple professional guidelines
- Review manufacturer's Instructions For Use
- Convene a multidisciplinary team to review
 - Processes
 - Identify where you are with “best practice”
 - Identify where there are gaps
- Determine that Policies and Procedures are in alignment with guidelines and IFUs
- Identify and act on next steps to improve endoscope reprocessing



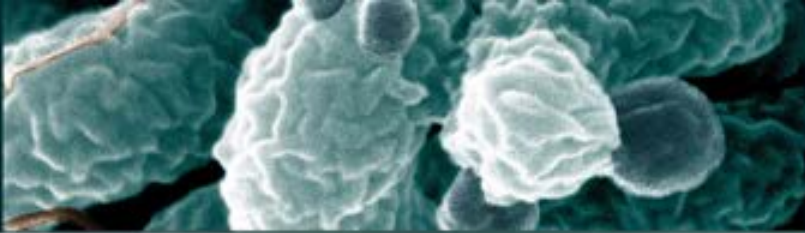
Summary

- Flexible endoscope reprocessing is a number 1 patient safety concern from the ERCI
- Auditing agencies are aware of this patient safety issue
- This issue requires multidisciplinary focus and execution to overcome the many challenges in getting it right the first time



The End





Questions?





References

- Alfa, M. J. & Nemes, R. (2003). Inadequacy of manual cleaning for reprocessing single-use, triple-lumen sphinctertomes: Simulated-use testing comparing manual with automated cleaning methods. *American Journal Infection Control*, 31(4), 193-207.
- Alfa, M. J., Sepehri, S., & Olson, N. (2012). Establishing a clinically relevant bioburden benchmark: A quality indicator for adequate reprocessing and storage of flexible gastrointestinal endoscopes. *American Journal of Infection Control*, 40(3), 233-236.
- Alfa, M. J. (2015). Monitoring and improving the effectiveness of cleaning medical and surgical devices. *American Journal of Infection Control*, 4(5 Supp), S56-S59.
- Brock, A. S., Steed, L. I., Freeman, J., Garry, B., Malpas, P., & Cotton, P. (2015). Endoscope storage time: Assessment of microbial colonization up to 21 days after reprocessing. *Gastrointestinal Endoscopy*, 82(5), 1150-1154.
- Edmiston, C. E. & Spencer, M. (2014). Endoscope reprocessing in 2014: Why is the margin of safety so small? *Association of Perioperative Registered Nurses*, 100(6), 609-615.
- Food and Drug Administration (2016). Retrieved from <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM430550.pdf>
- Ofstead, C. L., Snyder, A. K., & Horton, R. A. (2010). Endoscope reprocessing methods: A prospective study on the impact of human factors and automation. *Gastroenterology Nursing*, 33(4), 304-311.
- 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.
- Parente, D. M. (2007). Could biopsy port valves be a source for potential flexible endoscope contamination? *Infection Control Today*, 11(6).
- Pineau, L., Villard, E., Duc, D. L., & Marchetti, B. (2008). Endoscope drying/storage cabinet: interest and efficacy. *Journal of Hospital Infection* 68(1), 59-65.
- Pyrek, K. M. (2002). Nooks and crannies: The breeding grounds for bacteria. *Infection Control Today*. Retrieved from: <http://www.infectioncontrolday.com/articles/2002/06/nooks-and-crannies.aspx>