EDUCATION

STERIS UNIVERSITY

# Cleaning Challenges Related to Biofilms

One Integrated Approach to Healthcare.

STERIS

## Continuing Education Contact Hours

- Participants must complete the entire presentation/seminar to achieve successful completion and receive contact hour credit. Partial credit will not be given.
- STERIS Corporation is an approved provider of continuing nursing education by the CBRN (provider number 11681) for 1 contact hour along with ABCGN, CBSPD, and IAHCSMM.
- In accordance with CBRN guidelines, registered nurses must provide their state license number.
- All of the presenters are employees of STERIS Corporation and receive no direct compensation other than their normal salaries for participation in this activity.
- STERIS Corporation is providing the speakers and contact hours for this activity. However, products referred to or seen during this presentation do not constitute a commercial support by the speakers.

## Learning Objectives

After completing this continuing education activity, the participant will be able to:

- Review the formation of biofilms;
- Discuss the clinical relevance of biofilms; and
- Identify the sources and prevention of biofilm contamination in cleaning.

## What is Biofilm?

Structured community of bacterial cells enclosed in a self-produced polymeric matrix and adherent to an inert or living surface =

**SLIME**

- Bacteria, algae, yeast, fungi
- Living (teeth, intestinal walls)
- Nonliving (rocks, medical devices)
- Formed as continuous layers

Read more:
http://science.jrank.org/pages/872/Biofilms.html#ixzz0V5g9qOP2

## How Does a Biofilm Form?

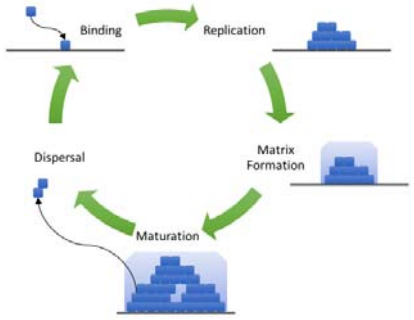
- Free floating microorganism recognizes and adheres to a solid surface
  - Aggregate into micro-colonies
- Build extracellular polymeric substances (EPS) matrix to
  - Increase adherence
  - Protect organism from environment
- Attracts other and different organisms
- Matrix expands and strengthens

## Biofilms

Four functional states

1. Attachment
   - Planktonic bacteria recognize and attach to surface
2. Micro-colonization
   - Bacteria aggregate and form micro-colonies
3. Biofilm formation
   - Chemical signals released and exopolysaccharide encasement begins
4. Detachment
   - Natural pattern of detachment to new location

## Biofilms, continued




## Aging Biofilms

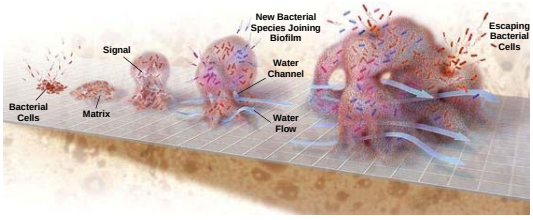
- Young Biofilm
- EPS Matrix is simplistic
- Geared to making stronger EPS matrix
- Monolayer formation or may have simple stacking
- Easiest to remove
- Allows cleaning agents, disinfectants, and sterilization processes

## Aging Biofilms, continued

Mature Biofilm

- Promotes migration of cells with colonization of new areas
- Complex EPS matrix and strong adhesion to surface
- Hardest to remove
- Resistant to detergents and antibiotics

## How Biofilms Form and How to Fight Them




**As condensed from "Battling Biofilms" by J.W. Costerton and Phillip S. Stewart appearing in Scientific American, July 2001.**

## Learning Objectives

After completing this continuing education activity, the participant should be able to:

- Review the formation of biofilms
- Discuss the clinical relevance of biofilms
- Identify the sources and prevention of biofilm contamination in cleaning

## Are Biofilms Good or Bad?

The Good Ones

- Elimination of sewage
- Biofiltration
- Bioreactors
- Intestinal microorganisms
  - Prevention of pathogenic microorganisms
  - Provide nutrition (in production of some amino acids and vitamins)

## Are Biofilms Good or Bad?, continued

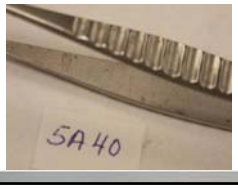
The Bad and Ugly

- Damage to surfaces
  - Bio-corrosion
  - Bio-fouling of lines
- Contamination of products
  - Reduced water quality
  - Foods
  - Devices
  - Waterlines
  - Manufactured drugs
- 65% of all microbial infections are due to Biofilms (National Institute of Health)

## Are Biofilms Good or Bad?, continued

Surface Contamination

- Most surfaces are not “micro” smooth
- Marks, scratches, etc.
- Can be difficult to clean, disinfect and sterilize




## Disease Linked to Biofilms

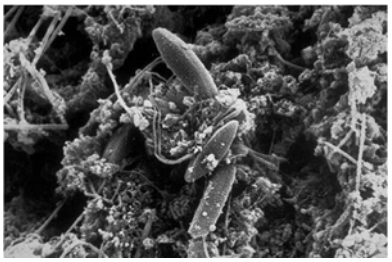
- Plaque
  - Tooth Biofilm
- Chronic Sinusitis
  - Parsek and Singh (2003) indicated that 80% of patients test positive for biofilm
- Outbreaks of *Pseudomonas aeruginosa* colonize alveoli of cystic fibrosis patients
- Study of children with Chronic Otitis Media: 92% demonstrated biofilms within the middle ear
- Ventilator acquired pneumonia
- Catheter-related blood stream infections
- Catheter-associated urinary tract infections

## Biofilms

| Microorganism | Associated Biofilms |
|---|---|
| Streptococcus mutants | Cause tooth plaque and periodontal disease. Layers of bacteria and polysaccharide growing on the teeth which can cause damage to teeth an gums |
| Pseudomonas aeruginosa | Most prevalent biofilms associated with water surface systems including water pipes, washing machines, water circulation systems. Industrial biofouling (corrosion and clogging) and nosocomial infections |
| Legionella pneumophila | Legionnaire’s disease associated with contaminated aerosolized moisture from air and heat cooling water distribution systems |
| Staphylococcus aureus Staphylococcus epidermidis | Skin and device related infections |
| Mycobacterium fortuitum Mycobacterium chelonae | Biofouling and water-borne infections or “pseudo” infections |
| Propionicacterium acnes | Often considered as the cause of acne, persistent skin infection, particularly in young adults |
| Deinococcus geothermalis | Biofouling of paper machines, impairs operation and product defects |
| Candida albicans | Most prevalent fungal-type biofilms, reported in device-related infections, root canal or endodontic infections |

## Where are the Biofilms?

## Biofilm on Stainless Steel Water Line



**Biofilms: Microbial Life on Surfaces**

**Rodney M. Dolan***

*Centers for Disease Control and Prevention, Atlanta, George, USA 2002

## Biofilms and Medical Devices

| Device | Microorganisms | Disease |
|---|---|---|
| Dentures | Candida | Thrush, abscesses |
| Lenses | Pseudomonas<br>Amoeba | Red eye, conjunctivitis<br>Corneal ulcers |
| Catheters | Staphylococcus,<br>Enterococcus, coliforms | Urinary tract infections<br>Peritonitis, bacteremia |
| Dialysis machines | Heterotrophs,<br>Cyanobacteria,<br>Pseudomonas | Kidney, liver infections<br>Bacteremia |
| Tampons | Staphylococcus | Toxic shock syndrome |
| Hip joints, etc. | Staphylococcus | Pain, trauma,<br>bacteremia |
| Arterial implants | Heterotrophies | Septicemia |

## Biofilms in Medical Device Lumens

- Contaminated endoscopes and accessories
- Contaminated automated endoscope reprocessors
  - –Within the processor
- Associated with water-feed systems
- Source
  - –Poor cleaning of lumens
  - –Ineffectual chemical disinfection
  - –Recontamination from water source

## Why are Biofilms Difficult to Eliminate?

Extracellular polymeric substance (EPS) matrix

- Polysaccharide material forms the matrix
- Noncellular materials stick to polysaccharide

## Learning Objectives

After completing this continuing education activity, the participant should be able to:

- Review the formation of biofilms
- Discuss the clinical relevance of biofilms
- Identify the sources and prevention of biofilm contamination in cleaning

## Biofilms

Strategies to combat biofilm

- Prevention
- Surfaces that discourage attachment
- New technologies that interrupt biofilm formation

## The Prevention of Biofilms

- Clean and dry lumens thoroughly
- Use cleaning agents with high enzyme activity
- Use appropriate disinfection agents
- Sterilize whenever possible
- Do not let bioburden dry on or in a medical device

## Why is 'Clean' Important?

- Cleaning failures affect patients
  - Microbial contamination
  - Toxic effects
  - Devices not disinfected/sterile
  - Devices damaged, nonfunctional
- Focus on importance of cleaning
- New technologies and processes

## Defining the Cleaning Process

"The removal, usually with **detergent** and **water**, of adherent visible soil,… from the surfaces,… and lumens of instruments,… equipment by a **manual or automated process** that prepares the items for safe handling and/or further decontamination."

Association for the Advancement of Medical Instrumentation (AAMI)

## Guideline for Cleaning and Care of Surgical Instruments


**Recommendation III:** Cleaning instruments as soon as possible after use can help prevent formation of biofilm and dried blood. When blood or other bioburden is allowed to dry on instruments, it can become more difficult to remove. The effectiveness of disinfection or sterilization can be compromised when thorough cleaning is not accomplished.

## The Role of Cleaning

**IAHCSMM (Central Service Technical Manual, 8th Edition)**

- *"*Cleaning refers to the removal of all visible and non-visible soil, and any other foreign material from the medical device being processed. It is the most important step in the disinfection/sterilization process. Instruments must be thoroughly cleaned and rinsed for subsequent reprocessing steps to be effective.*"*

**CDC (Guidelines for Disinfection and Sterilization in Healthcare Facilities)**

- *"*Thorough cleaning is essential before high-level disinfection or sterilization because inorganic or organic materials that remain on surfaces of instruments interfere wit the effectiveness of these processes.*"*

**SGNA (Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes)**

- *"*Manual cleaning… is the first and most important step… Retained debris may inactivate or interfere with the capability… to effectively kill and/or inactivate microorganisms.*"*

**If it isn't clean… it can't be disinfected or sterilized.**


Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
Guidance for Industry and Food and Drug Administration Staff

It is important to note that cleaning, disinfection, and sterilization are distinctly different processes.

Cleaning is the physical removal of soil and contaminants; the methods and agents used for cleaning should be designed to remove such soil and contamination effectively. Effective cleaning should: minimize the soil transfer from one patient to another or between uses in a single patient; prevent accumulation of residual soil throughout the product's use life; and allow for successful, subsequent disinfection/sterilization steps.

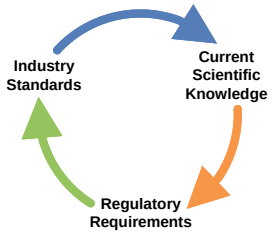
## Scientific Knowledge

The type of decontamination required for a particular contaminated device depends on the biohazard that the device presents. The cleaning and/or microbicidal process appropriate for a particular device depends on:

- Device manufacturer's written instructions
- Chemical Instruction
- Level of microbial kill
- Design of the device

## The Role of Cleaning Manually

- Skills competencies
- Sustain environment for repeatable results

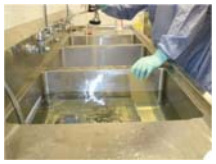



## Factors and Conditions in Cleaning

- Type of microorganisms present
- Bioburden load
- Water quality
- Complex medical devices
  - Difficult to disassemble
  - Complicated instructions
  - Instructions Accessibility to intricate parts

## Cleaning – A Quick Review

- Achieve effective cleaning
- Removal of gross soil
- Pre-treatment at point of use
- Appropriate cleaning methods



## Broad Spectrum Cleaning Efficacy

Soils

- Proteins
- Fats and Lipids
- Carbohydrates
- Synthetic
- Inorganic

## Ineffective Soil Removal

- Ineffective cleaning products can require extensive cleaning
  - Result in damage and scratches
- Residual soil can:
  - Foster biofilm formation
  - Trap cleaning chemistry
  - Cause damage to instrument surfaces

## The Types of Cleaning Process

Manual Process

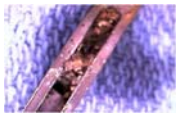
- Chemical dilution rate
- Water temperature
- No disinfection
- Splash/Aerosolization

Automated Process

- Automated dilution
- Automated process
- Thermal disinfection
- Washer testing

## Manual Cleaning

- Follow manufacturer's instructions
- Disassemble
- Physical action
  - Cleaning accessories
  - Remove visible soil



## Manual Cleaning of Endoscopes

- Pre-clean, flush channels at point of use
- Follow manufacturers IFU
- Leak Test
- Submerge endoscope
- Cleaning chemistry
- Access/brush all channels
- Proper size brushes
- Rinse thoroughly

## Automated Endoscope Washer/Disinfectors

- Wash/rinse phase
- High level disinfection/rinse/dry
- Types of high level chemical disinfection
- Aldhyde Solutions
  - Glutaraldehyde, OPA, etc.
  - Toxic but effective
- Oxidative Solutions
  - Hydrogen peroxide and peracetic acid
  - Non-toxic and effective

## Endoscope Transmission Prevention Strategies

Disinfection

- M. Alfa and R. Howie (2009) demonstrated that glutaraldehyde solutions promoted the production of buildup biofilm within the lumens of endoscopes
  - Oxidative solutions contributed less to buildup
  - Enzymatic cleaning solutions can provide food source for formation of biofilms

## Automated Cleaning

- Adjunct to manual cleaning
- Decreases manual labor, exposure to pathogens
- Standardized according to set parameters
- Cycles validated by manufacturer
- Outcome standardized

## Automated Cleaning, continued

- Automatic cleaning and rinsing
- Removes soil and microorganisms
- Methods
  - Ultrasonic cleaning systems
  - Washer-disinfectors, washer-decontaminators
  - Cart and utensil washers
  - Automated Endoscope Reprocessors (AERs)

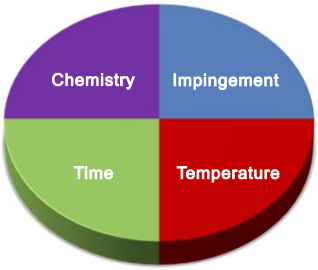
## Automated Washer Disinfector Cycle Phases

- Pre-wash
- Pulsed enzyme
- Wash
- Neutralizer
- Rinse
- Thermal rinse
  - Renders “safe for handling”
- Dry

## The Washing Equation

**Parameters for Clean Outcomes**

- Time
- Temperature
- Chemistry
- Impingement




## Parameters for Automated Cleaning

- Each phase of cycle critical to end result
- Timing phase depends on other parameters
- High automated spray force and high wash temperature shortens cycle time
- Low automated force and low wash temperature increase cycle times
- Cleaning chemistry depending on water quality, impingement, temperatures

## Washer Disinfector Maintenance

- Clean screen at least daily
- Spray arms
- Decontaminate per the manufacturers IFU

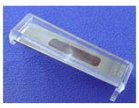
## Automated Washer Verification

**Is the Process Working?**

- The instruments are visually clean
- The instruments are disinfected
- The instruments are functional
- The washer is working properly

## Quality Control

- Monitor automated cleaning equipment
  - Installation and/or major repairs
  - Each day used
- Monitor/verify process
  - Review printout
  - Initial each cycle
- Devices traceable to patients



## Residual Soil

- Incorrect cleaning chemistry
- Complex device design
- Causes damage to instrument surfaces
  - Loss of passive layer can harbor bacteria
- Reduces effectiveness of HLD or sterilization
- Device “not safe to handle”
- Fosters biofilm formation

## Ultrasonic Cleaning Systems

- Remove gross debris first
- Used for fine cleaning
  - Ophthalmic or cardiovascular
  - Ortho grinder, cutters and reamers
- Thorough cleaning of hard-to-reach areas
- Lifts grease, fats, lipids and/or proteins

## Action Plan

- Educate your staff members on prevention of biofilm formation
- Enforce adherence to recommended guidelines for cleaning of medical devices
- Develop SOP’s and cleaning competencies for medical devices and durable medical equipment

## References


- Alfa, M. J., & Howie, R. (2009). Modeling microbial survival in buildup biofilm for complex medical devices. *BioMed Central Infectious Diseases, 9*, 56.
- American National Standard/Association for the Advancement of Medical Instrumentation (2017). *ANSI/AAMI ST79:2017: Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Arlington, VA: Author.
- Association of periOperative Registered Nurses. (2016). Hand hygiene *Guidelines for perioperative practice*. Denver, CO: Author.
- Balotescu, C., Israil, A. M., Lazar, V., Cernat, R., Petrache, L. M., & Dinu, C. (2002). [Study of antibiotic influence on adherence capacity of gram positive and gram negative bacteria to the cellular substrate]. *Bacteriol Virusol Parazitol Epidemiol, 47*(3-4), 131-135.


## References, continued


- Balotescu, C., Israil, A. M., Lazar, V., Cernat, R., Petrache, L. M., & Dinu, C. (2002). [Study of antibiotic influence on adherence capacity of gram positive and gram negative bacteria to the cellular substrate]. *Bacteriol Virusol Parazitol Epidemiol, 47*(3-4), 131-135.
- Bisset, L., Cossart, Y. E., Selby, W., West, R., Catterson, D., O'Hara, K., & Vickery, K. (2006). A prospective study of the efficacy of routine decontamination for gastrointestinal endoscopes and the risk factors for failure. *American Journal Infection Control, 34*(5), 274-280.
- Eick, S., & Pfister, W. (2004). Efficacy of antibiotics against periodontopathogenic bacteria within epithelial cells: an in vitro study. *Journal Periodontology, 75*(10), 1327-1334.
- Hall-Stoodley, L., & Stoodley, P. (2009). Evolving concepts in biofilm infections. *Cellular Microbiology, 11*(7), 1034-1043.


## References, continued


- International Association of Healthcare Central Service Material Management. (2016). *Central Service Technical Manual* (8th ed.). Chicago, IL: Author.
- Levin, A. S. (2009). Nosocomial legionellosis: prevention and management. *Expert Review of Anti -infective Therapy, 7*(1), 57-68.
- Marion, K., Freney, J., James, G., Bergeron, E., Renaud, F. N., & Costerton, J. W. (2006). Using an efficient biofilm detaching agent: an essential step for the improvement of endoscope reprocessing protocols. *J Hosp Infect, 64*(2), 136-142.
- Sampson, M. N. (2008). Effectiveness of Hypochlorous Acid and Glutaraldehyde High Level Disinfectants against a Pseudomonas aeruginosa AER Biofilm Test Model. *American Journal of Infection Control, 36*(5), E20-E21.

## References, continued


- Stiefel, P., Mauerhofer, S., Schneider, J., Maniura-Weber, K., Rosenberg, U., & Ren, Q. (2016). Enzymes Enhance Biofilm Removal Efficiency of Cleaners. *Antimicrobial Agents Chemotherapy, 60*(6), 3647-3652.
- Vickery, K., Ngo, Q. D., Zou, J., & Cossart, Y. E. (2009). The effect of multiple cycles of contamination, detergent washing, and disinfection on the development of biofilm in endoscope tubing. *American Journal Infection Control, 37*(6), 470-475.
- Vickery, K., Pajkos, A., & Cossart, Y. (2004). Removal of biofilm from endoscopes: evaluation of detergent efficiency. *American Journal Infection Control, 32*(3), 170-176.


## Handouts

To access the handouts for this presentation, go to: university.steris.com/bio