LEARNING OBJECTIVES
1. Define biofilm
2. Review cleaning processes that effectively remove biofilm
3. Discuss methods to validate cleaning effectiveness

THE BEST ATHLETES KNOW THAT TO DEVELOP TEAM STRATEGIES to defeat their opponents, they must know as much as they can about those opponents. This includes who they are, what is important and, if possible, how they will play the game. In sports, the “who” is easy – members of the opposing team – and the “what” is also known: winning in a sportsman-like manner. The “how” can be determined from experience in previous games and/or input from others who have seen the opposing teams play.

At work, biofilm is one of the most important challenges that confront Central Service (CS) technicians. Although it was first identified in the 1600s, its importance to CS personnel and its impact on the instrument processing cycle have only been identified and confirmed within the past few years. As with athletes, CS technicians must know as much as possible about this formidable opponent in order to be victorious over it.

OBJECTIVE 1: DEFINE BIOFILM
Biofilm is a collection of microorganisms that attach to surfaces and each other. Biofilm prevents antimicrobial agents, such as sterilants, disinfectants, and antibiotics, from reaching microorganisms, and is difficult to clean from contaminated instrumentation and processing equipment.

Biofilm can form on many types of surfaces, especially those that are moist and in regular contact with water. Biofilm forms into colonies, which may contain multiple types of microorganisms, including bacteria, yeast and fungi. As the colonies grow, they secrete a protective gel around themselves, which is very difficult to penetrate.
Biofilm is a generic term that describes a variety of substances, some with everyday names found in many places. For example, helpful types of biofilm include those that assist with treatments of sewage and contaminated soil, and others used for the clean-up of oil and gasoline spills. Dental plaque, pond scum and the slimy coatings on water pipes and toilet tanks are examples of not-so-helpful forms of biofilms. Biofilm that has had uninterrupted time to grow and multiply when forming pond scum and dental plaque can be easily seen with the naked eye; However, biofilm usually cannot be seen on reusable medical devices without the use of a microscope.

Cleaning biofilm from instruments is very difficult because the detergents have a difficult time penetrating the protective gel formed around the biofilm colony. Instruments should be cleaned as soon as possible after use.

Biofilm diseases and infections in humans, including ear infections, tonsillitis, and some chronic and implant infections. Some studies have also reported a link between biofilms and cystic fibrosis. They can also be found on the inside of contact lenses and within human organs. Biofilms can be life-threatening to people with compromised immune systems.

OBJECTIVE 2: REVIEW CLEANING PROCESSES THAT EFFECTIVELY REMOVE BIOFILM

Biofilm develops in five stages, beginning when a planktonic (free-floating) micro-organism attaches to a surface and ending when a mature colony releases free-floating cells to spread in the environment.

The National Institutes of Health (NIH) states that biofilms are very difficult to treat with antimicrobial agents for reasons that are not fully understood. Bacteria within biofilms can be up to 1,000 times more resistant to a given agent than their counterparts that are not part of a biofilm colony. This obviously means that it is easier to clean devices before biofilm can form on them.

Some simple steps to stop or minimize biofilm formation include:

• Keep things dry. Since biofilm likes a moist environment, it is less attracted to dry areas. Do not let instruments remain in solutions longer than recommended by the instrument and solution manufacturers. Carefully dry instruments after cleaning; Countertops and work surfaces, and especially hard-to-reach surfaces, should be cleaned, disinfected and dried at the end of each shift;

• Ensure items have been adequately rinsed with pure rinse water because biofilms will connect with mineral residues left on surfaces;

• Hang scrub brushes and cleaning tools when they are not in use. This keeps them away from moisture and allows them to dry, which decreases opportunities for biofilm formation;

• Do not refill containers, especially those that previously contained lotions or soaps. Note: although combining solutions from several partially-filled containers may seem cost-effective, this process increases the risk of biofilm formation.

Cleaning biofilm from instruments is very difficult because the detergents have a difficult time penetrating the protective gel formed around the biofilm colony. Instruments should be cleaned as soon as possible after use. Removing gross soil and flushing lumens at the point of use helps the decontamination process by decreasing opportunities for biofilm formation. Careful observance of cleaning instructions is the best defense against biofilms.

In May, 2011, the U.S. Food and Drug Administration (FDA) issued a Draft Guidance for industry and FDA staff. This document is designed for manufacturers of reusable medical devices, and it outlines test soils and an acceptance protocol for the cleaning process. Once the instrument manufacturer has validated an effective cleaning process, it should always be followed.

Instruments with lumens, such as suction tubes and flexible endoscopes, are more difficult for CS technicians to clean than many other instruments, and biofilm can develop quickly. Therefore, it is important to ensure these items are properly
cleaned. Insulated instruments that have not been properly maintained are also a cleaning concern because damaged insulation encourages biofilm formation.

Always follow the manufacturer’s Instructions for Use (IFU) for each instrument being cleaned. IFU contain important information relating to water quality and appropriate types of cleaning solutions with proper dilution instructions. Recommended water temperature, soak times, and cleaning and rinsing instructions are also included in the IFU. Note: IFU should always be kept in each area of the department where instruments will be handled. The IFU should be easy to access, especially in the decontamination, assembly, and sterilization areas.

Meticulous manual preparation prior to mechanical cleaning is essential for most instruments. Always use the proper brush when cleaning lumens and ensure that the brush is the proper length (it should be able to pass through the entire lumen). Also, ensure the brush is the proper diameter. If it is too small, it will not properly clean all inner surfaces of the lumen; if it is too large, it may damage the lumen.

After cleaning, the IFU procedures for proper inspection, lubrication and assembly should be followed. Storage instructions should also be followed, especially for lumened instruments, such as flexible endoscopes. If the manufacturer’s IFU are not clear, seek clarification. Do not assume that the cleaning instructions are the same as those for a similar instrument made by another manufacturer.

Instruments are not the only place biofilms may develop in the CS department. For example, mechanical equipment, such as washer decontaminators, can become colonized and contaminate instruments during the cleaning process. As with instruments, always follow the manufacturers’ IFU for the proper cleaning and descaling of all decontamination equipment.

**OBJECTIVE 3: DISCUSS METHODS TO VERIFY CLEANING EFFECTIVENESS**

After items have been cleaned, it is important to verify that the cleaning process was effective. While CS technicians should know the importance of visual inspection, they must also remember to use a magnifying glass or other visual enhancing equipment to inspect serrations, box locks, ratchets, and other hard-to-see areas on instruments.

Even with the use of most visual enhancing tools, microorganisms will still not be seen, and other tests have been developed to help verify that cleaning quality standards have been attained. Examples of tests that can be used to verify lumen cleanliness include:

- Cameras and other devices. Note: while this verification method is one of the most effective, it is also the most expensive.
- Fleece-type pipe cleaners made for instrument inspection. If organic soil is present on the pipe cleaner as it exits the lumen, the instrument must be returned to the decontamination area for re-cleaning.
- The flush method. There are several ways to inspect instruments using this inexpensive process. For example, the lumen or cannulated item can be flushed with 3% hydrogen peroxide. If bubbling is seen, this means the device is not clean. If no bubbling is present, the instrument will still need to be re-cleaned to remove the residual hydrogen peroxide. It is important to check the instrument’s IFU to determine if it can be tested in this manner because hydrogen peroxide can damage the finish of some instruments.

Commonly-prepared tests can be used to verify instrument cleanliness and the potential presence of biofilm colonies. Two of the most common used in hospital protocols are protein tests and adenosine triphosphate (ATP) bioluminescence tests, both of which test for residual soils and for biofilm.

**Protein tests** use the flush method. Lumens are flushed with sterile water, which is captured as it exits the lumen. A commercially-prepared test strip is then used to test the solution for various organic soils, such as blood and protein. This process may help detect the presence of biofilm and assess instrument cleanliness.

A swab method can also be used to test for organic soils, such as blood or protein, and this process is also an effective and easy way to check for cleanliness and biofilm on many types of instrumentation. Like the flush method, several commercial products are available. For example, kits may be purchased to test for either blood or protein matter, and the testing method is the same for either residue. First, a commercially-prepared swab is passed through a lumen or over an instrument. The swab is then placed in a vial of solution supplied with the kit. The vial is then capped and shaken and, if residual blood or protein is present, a color change will be seen on the swab.

**ATP bioluminescence tests** use the swab method to detect ATP found in animal, plant, bacterial, yeast, and mold cells. Note: ATP is a substance that is the primary source of energy for all cellular reactions. Residues, such as blood and bioburden (microorganisms on a contaminated object), contain large amounts of ATP. After cleaning, all sources of ATP should be significantly reduced.

After swabbing the lumen or outside of an instrument, the swab is either placed into a cartridge or is combined with a
reagent; the test swab is then placed into a meter or is read by a hand-held monitor to determine the presence of ATP.

Monitoring mechanical cleaning equipment is also important to ensure optimum cleaning efficiency. AAMI ST79 states that mechanical cleaning equipment should be tested at least weekly, and the test should involve more than one function.

All mechanical equipment should be tested for water quality, pH level and temperature. Ultrasonic cleaners should be tested for cavitation action, and washer decontaminators should be tested for protein removal. Other tests that may be run include those for detergent levels and cycle times. Ensuring that mechanical equipment works efficiently helps ensure instruments will be properly cleaned and that biofilm will not have a friendly growth environment.

IN CONCLUSION

CS technicians have always had an important job in instrument processing. As instruments become more sophisticated and complex, the cleaning and assembly tasks have become much more difficult and time consuming. Biofilm has added to this complexity as they are invisible, and the gel-like substance they secrete for protection is very resistant to cleaning and disinfection chemicals.

Biofilm has been linked to many types of hospital-acquired and surgical site infections, and there is a growing concern regarding the ability to consistently and effectively destroy their colonies. Manufacturers’ IFU for cleaning must be available and closely followed at all times. Shortcuts cannot be taken, work areas must be kept as clean and dry as possible, and meticulous manual and mechanical cleaning is a constant necessity. Other requirements include the need to test cleaned instruments for cleanliness and ensure that instruments are properly dried, assembled and, in some cases, stored.

REFERENCES

1. See, for example: http://mpkb.org/home/pathogenesis/microbiota/biofilm
2. FDA. Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.

ADDITIONAL REFERENCES


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