SELF-STUDY SERIES

The case for residual soil detection testing

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Years ago, if you had asked me what ‘CSI’ stood for, I might have said, “That stands for the College of Southern Idaho.” Today, thanks to some very popular television shows, I would say, “CSI stands for crime scene investigator.” Crime scene investigators (CSIs) have an interesting job. They walk through a crime scene and collect evidence without knowing if there is any evidence present or not. CSIs play an important role in ensuring that the perpetrator of the crime is arrested and convicted. “Crime scene investigators must be able to apply scientific methods, techniques, and knowledge in the application of the law and recognize the intricacies involved with the examination of physical evidence at the crime scene.” Once the evidence is collected, it is identified and evaluated by forensic scientists.

Medical practitioners began using forensic science in the 16th century. In the late 18th century the first evidence of modern pathology was revealed, and in 1909 the first school of forensic science was established. You may by now be asking yourself, “What does forensic science have to do with sterile processing?” These departments are not typically crime scenes. But there is a connection: there are tools and techniques available to sterile processing professionals (SPPs) that are like the tools and techniques used by CSIs.

Like CSIs who must collect all evidence that can lead to prosecuting the right criminals, SPP’s must collect and document evidence that the surgical instrumentation they process is thoroughly cleaned and sterilized before use on the next patient. If they don’t, they put patients at risk for a surgical site infection (SSI). There are SSI risk factors that are out of SPD personnel’s control, such as patients who are immunocompromised or have heart disease, or who are diabetic or obese. There are also surgical procedures that have a higher rate of SSI (i.e., open-heart, gynecologic or lower GI surgeries). However, there are risk-reducing efforts that are easier to control, such as antibiotic stewardship policies, hand-hygiene programs and instrument processing procedures. There are standards, guidelines and new technologies that help SPPs assure that they deliver clean, sterile and complete instruments sets to the OR on time, every time.

If it’s not clean it can’t be sterilized

Dirty medical devices, regardless of where they are processed (e.g., central services, outpatient surgery or endoscopy departments) are first delivered to the decontamination area/room where they are cleaned and decontaminated before they go to the assembly area for inspection, instrument set assembly and packaging, and then on to be sterilized or high-level disinfected. Since all SPD professionals know the statement, “if it’s not clean it can’t be sterilized,” they must continually answer the question, “Are these instruments really clean?” before they let devices leave the decontamination area. Even if no soil is visible to the naked eye, the instrument may still be contaminated. So, the corollary to the first question is; “How do we verify that the instruments are clean and ready for the next step in the manufacturer’s reprocessing IFU?” The answer: we measure and evaluate residual contaminants on medical devices after completing the established cleaning protocol.

The responsibility for developing and validating methods for effective reusable medical device processing falls to the device manufacturer. Further, they are expected to test and validate any labeling claims of “fitness for reuse that are provided in the written instructions for the handling, cleaning, disinfection, packaging, and sterilization of medical devices in a health care facility.” The manufacturers of cleaning agents also must demonstrate compliance with their label claims. “They [too] must validate that their cleaners provide the expected level of soil removal and determine its materials compatibility.”

Based on published recommended practices or guidelines, published data on the

LEARNING OBJECTIVES

1. Discuss the value of residual soil testing.
2. Differentiate between protein testing and ATP testing.
3. Develop a quality program that includes protein testing as a component of verification of the cleaning process.
cleaning efficacy for the medical devices, and the validated recommendations of both the reusable device manufacturer and the cleaning agent manufacturer, SPDs are responsible for establishing a documented cleaning policy and procedure for the reusable medical devices they process.

Evaluation techniques
There are many techniques used to evaluate the results of the cleaning process. The most common, well known, and routinely executed one is visual inspection for visible organic soil (blood, tissue, fat). Often the SPP will use a magnifying glass for external surfaces and a borescope camera for inspecting internal channels of lumened devices. Unfortunately, even if a device looks clean to the inspector, residual organic soil and microbial contamination could be present on an accessible surface that could lead to cross-contamination, infection, granulomas and biofilm fixation.

Cleaning verification of external surfaces and inner channels of instruments with lumens or non-sealed tubular components is not possible by direct visualization alone. Therefore, it’s recommended that SPPs regularly test the cleaning efficacy of automated washers and ultrasonic cleaners, and that they verify the efficacy of the cleaning process immediately after cleaning in such a way as to not damage the device or require re-cleaning.

There are several tests used to detect non-visible soil “markers:”
- The adenosine triphosphate (ATP) test.
  ATP is an energy-carrying molecule present in the cells of all living things. However, when the cells die, the concentration of ATP decreases over time; this may make detection less accurate.3
- The hemoglobin test. This test was originally designed to detect blood in stool, but has also been developed as a bioburden detection tool for sterile processing functions.
- Protein testing to detect amino acids (small subunits of a large protein molecule). Forensic scientists use a chemical called ninhydrin, which reacts with amino acids to expose latent fingerprints that are invisible to the naked eye.

Commercial residual organic soil tests
ATP testing has been used in the food service industry for more than 30 years.4 More recently, ATP testing is being used in the healthcare industry. ATP tests indirectly measure residual organic matter. They require the use of a luminometer to measure relative light units (RLU). A higher RLU indicates more residual ATP, and a lower RLU means there is less ATP on the device.

Hemoglobin testing detects blood, but because it was designed to check for blood in stool, it is far too specific and sensitive. Hemoglobin testing measures down to 0.1 microgram and is so sensitive that it does not detect other proteins, such as bone marrow, muscle tissue, placenta, nails, hair and organs.

Protein soils are the most common surgical soils, and any invasive procedure will encounter protein, so it makes sense to test for residual protein on reusable medical devices. Proteins are difficult to remove from reusable medical devices in general, but if they have been allowed to dry they are even harder to dislodge. Since there are many proteins encountered during invasive procedures, a protein test that detects a broad spectrum of protein-based substances is optimal.

There are seven recommendations found in Annex D of ANSI/AAMI ST79 for cleaning verification tests. The recommendations are that the test be:
1. Rapid
2. Easy to perform
3. Sensitive (i.e., meet realistic benchmarks)
4. Accurate
5. Repeatable
6. Free of interfering substances
7. Robust (i.e., do not require exacting conditions or time constraints that cannot be achieved in routine reprocessing areas)

Clinical consequences
Healthcare-associated infections (HAIs) and associated outbreaks have been newsworthy events across the country in recent years. Many of those outbreaks have been traced back to insufficiently cleaned devices such as arthroscopic shavers, suction tubes and flexible endoscopes, all of which are difficult to clean. HAIs are estimated to cost between five and 29 billion dollars per year.2 Surgical site infections (SSIs) continue to occur at a rate of 1 in 7 cases.

Operating rooms today are busy, fast-paced environments in which one surgical procedure may use multiple instrument sets. A single instrument set may have more than 50 components; multiply that by 4-8 sets per case, and cleaning verification is no longer an option but an integral requirement of the process.

Reusable medical device designs are far more complex than in previous years, and with that complexity comes new cleaning challenges. There are numerous cracks, crevices, lumens, channels and a host of other places that provide hiding places for bioburden if they aren’t properly cleaned. Residual soil can contribute to SSIs and other complications. For example, residual protein may trigger an allergic reaction in some patients. Having the full assurance that your cleaning methods are effective is imperative. A quality control measure such as residual soil detection testing is a wise addition to your department’s quality management program.

As reusable medical devices become more complex, methods and inspections post-decontamination also become more challenging. The ANSI/AAMI ST79:2017 document is an invaluable resource to the SPP. Included with the document are informative annexes. Annex D, User verification of cleaning processes, outlines each step of the cleaning process, which must be based on manufacturers’ written instructions for use (IFU) and followed in their entirety.

Manufacturers are responsible for developing cleaning processes that address the types of contamination that will be encountered during patient use. The human body has roughly 10,000 different proteins found in virtually every area, so protein is a commonly used marker for cleaning efficacy evaluation.

Selecting the appropriate test
Number six of the seven recommended features of cleaning verification tests in Annex D is that the test be free of interfering substances. An example of an interfering substance is sodium dodecyl sulfate (SDS) solution, which can cause inflammation in some patients. The procedure to collect eluting samples from endoscopes, ophthalmic instruments, and devices used in the middle or inner ear can put a patient at risk of injury if the test kit manufacturer’s written IFUs to re-clean the device (to ensure removal of the SDS solution) are not followed explicitly. If your test product IFU requires re-cleaning, then it does not meet the first recommendation, which is that the test be rapid.

The use of sterile normal saline and delivery of rapid results makes modern protein testing user-friendly. The benefit of a test that uses saline is that it does not require re-cleaning. Protein tests are designed to be easy to perform (feature #2).
Those protein detection tests that use saline and a clean or sterile collection device (swab, brush or squeegee) to obtain the sample are free of interfering substances (feature #6); they are, when performed correctly, also accurate (feature #4) and robust (feature #7).

It’s not unusual for ATP detection testing and protein detection testing to be confused with one another. Unlike ATP testing, which loses its detectability over time, protein detection remains constant because protein is present on the device until it is removed.

**Quality control**

Quality control measures assure SPPs that the processes and procedures they follow are effective (doing what they are intended to do, which is to thoroughly clean reusable medical devices). Cleaning verification adds measurable, documentable control and consistency to the reprocessing function.

SPPs should verify that their instruments are clean after going through any automated cleaning equipment. They should also monitor the performance of all automated equipment (i.e., washer/disinfectors and ultrasonic cleaners) as a part of their department’s quality systems. In addition, all delicate instruments that are not processed in an automated washer should be tested for residual soils on external and internal surfaces after manual cleaning is performed.

**Optimal tests for optimal patient safety**

As the CSI collects evidence at the crime scene, so must the SPP collect and document evidence to verify that instruments are clean. Commercial residual soil tests are available for use in the SPD. In addition to visual inspection, they provide a more objective and sensitive approach to verifying if there is residual bioburden. But there are differences among them. ATP, a common testing method, has limitations; it is not rapid; it requires the purchase of additional equipment; and it may not be accurate. The hemoglobin test is very sensitive to blood but not to other proteins. Protein detection tests can be a better choice than ATP and hemoglobin tests because they detect protein, which is the most widely encountered soil; they are easy to perform; and they give rapid results. In addition, protein detection tests don’t require the purchase of additional equipment and are free from interfering substances, which eliminates the need for re-cleaning. The tests you select to use should be part of an overall quality system that adds control and consistency to your reprocessing functions, so that you can reduce infection risk and help assure better outcomes for your patients.

References:

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1. There are factors that can increase or reduce the risk of SSI. Factors that are controllable have the potential to:
   a. Increase the risk of SPP
   b. Reduce the risk of heart disease
   c. Help reduce the risk of SSI
   d. A and C

2. ANSI/AAMI ST79:2017 addresses cleaning verification in
   a. annex d
   b. annex a
   c. The information is not contained in this document.
   d. annex b

3. One reason protein soil markers are used to test for verification of cleaning processes is because they detect such a broad range of soil types.
   a. True
   b. False

4. When selecting a product for cleaning verification take into consideration:
   a. That it is rapid and easy to perform
   b. Will not damage the device
   c. Ideally will not require re-cleaning after testing
   d. All the above

5. Regular testing of the cleaning equipment that will be used on reusable devices before protein testing is part of the overall process of cleaning verification.
   a. True
   b. False

6. Protein testing is often confused with ATP Testing because ATP is also a component of living cells. Unlike ATP testing, which loses its detectability over time, protein detection remains constant because protein is present on the device until it is removed.
   a. True
   b. False

7. Manufacturers are responsible for developing cleaning processes that address the types of contamination that will be encountered during patient use. The soil marker of choice for cleaning verification is
   a. ATP
   b. Hemoglobin
   c. Protein
   d. all the above

8. Determining how to clean a device is defined by
   a. The main facility of a healthcare system.
   b. The lead tech or supervisor will write a procedure.
   c. The manufacturer of the device and the IFU
   d. A and C

9. Protein sampling for testing is usually acquired with a
   a. Swab
   b. Brush
   c. Squeegee
   d. Any of the above

10. When visible debris is found, or a protein test reveals a positive result, the device must be
    a. Re-cleaned at the prep station with alcohol
    b. Returned to decontamination for full reprocessing
    c. Both A and C
    d. Pushed to the assembly area

Circle the one correct answer:  

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