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INSIDE THE CURRENT ISSUE

August 2015

Operating Room

New cleaning and sterility assurance products boost efficiency, safety

by Kara Nadeau

A common saying among central service/sterile processing department (CS/SPD) professionals is: "If it's not clean it can't be sterile." With many hospitals attempting to do more with less, including the use of limited instrumentation for an increasing volume of surgical procedures, the CS/SPD faces greater pressure to turn around cleaned and sterilized equipment quickly and safely, which is no easy task.

In this month's CS Connection, we present some of the latest technologies to help CS/SPD professionals effectively and efficiently confirm cleanliness and assure sterilization has been achieved, as well as instrument processing best practices from industry experts.

The need for clean

While it is common knowledge that an instrument must be cleaned before it can be sterilized, achieving cleanliness can be a complex, multi-step process. Fortunately, there are many products available to help CS/SPD professionals confirm cleanliness during the processing cycle — from pre-cleaning to disinfection through to sterilization.

Manual cleaning

"The challenges to ensure sterility begin during the time of instrument transport from the OR back to the SPD," said Dave Daggy, Manager, Business Development, [Serim Research Corporation](#). "Bioburden and blood contaminants can become a problem if the instrument isn't introduced soon after the surgery to a pre-cleaning/transport solution such as an enzymatic detergent. Upon arrival at the SPD, the proper procedures for manual cleaning and ultrasonic or washer disinfectant operation should be followed according to department guidelines and the IFUs from the manufacturers of detergents and equipment."

Serim Research Corporation recently introduced its PINNACLE Monitor for Manual Enzymatic Cleaning Process (MEC), which determines the presence of active enzymes in manual bath cleaning solutions and guards against using improperly stored, improperly diluted or inactive enzymatic detergents. It also indicates that the degraded detergent use solution should be replaced. The MEC is a companion to the PINNACLE Monitor for Automated Cleaning Process

Outpatient Connection

Best practices for instrument processing

Central service/sterile processing (CS/SPD) expert, Chuck Hughes, Vice President of Infection Prevention and Consulting Services for Cantel Medical and the lead educator for Crosstex/SPSmedical, a Cantel Medical Company, offers up the following best practice steps, urging hospitals to ensure each step is understood and followed by all healthcare personnel who handle reusable devices:

- 1. Point of Use** – Remove gross soil during the surgical procedure, contain instruments properly during transport and apply pre-soak solution to keep instruments moist.
- 2. Decontamination** – Wear appropriate personal protective equipment (PPE) to clean soiled instruments as soon as possible in a designated area according to their written instructions for use (IFU).
- 3. Inspect and Package** – Inspect each instrument for cleanliness and function, package in FDA approved pouches, wrappers and/or rigid sterilization containers.
- 4. Sterilization** – Load the sterilizer properly and confirm the cycle type and parameters to meet each instrument's written IFU. After processing, allow packages to cool to room temperature (75°F) prior to handling.
- 5. Storage and Delivery** – Store in a dedicated area that is clean and restricts traffic. Prior to distribution, inspect each package for damage and proper external chemical indicator color change.
- 6. Quality Assurance** – Verify

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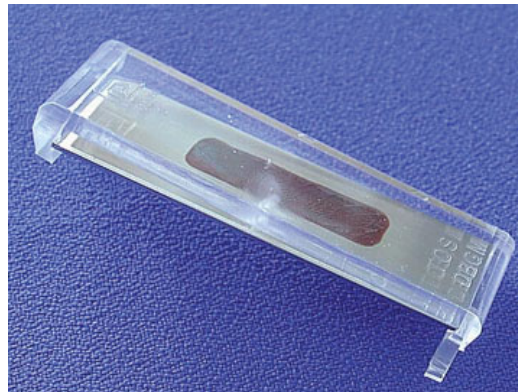
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(AEC) that monitors cleaning of washer-disinfectors and ultrasonic cleaners that use enzymatic detergents. This test has been shown to be most sensitive to changes in the enzymatic activity and concentration of the detergent along with changes in the wash cycle time, temperature and mechanical action of the cleaning unit.¹

"If it's not clean, it won't be sterile," said Daggy. "Understanding the need for and appropriate use of cleaning monitors, also known as challenge devices, during the cleansing process may be overlooked but is an important step in assuring cleaning and sterilization. Challenge devices are available to help SPD staff monitor the cleansing process. These monitors along with staff training will help ensure proper cleaning in a timely manner."

How clean is your cleaner?



Healthmark's TOSI washer test

While it is tempting to assume automatic washers/disinfectors are adequately cleaning surgical instruments and devices, it is critical that CS/SPD staff regularly monitor their effectiveness. There are numerous cleaning verification products on the market today to ensure washers/disinfectors are operating as intended.

For example, CS/SPD professionals can reveal the hidden areas of instruments using Healthmark's TOSI washer test, the easy to use blood soil device that directly correlates to the cleaning challenge of surgical instruments. According to the company, TOSI is the first device to provide a consistent, repeatable and reliable method for evaluating the cleaning effectiveness of the automated instrument washer.

"This is possible, because the blood soil is manufactured to exacting specifications each and every time," said Matthew Smith, Marketing Manager at Healthmark Industries. "When metered onto the stainless steel plate, the TOSI is completely analogous to a stainless steel instrument soiled with dried blood. Placed in the see-through plastic holder, the challenge is identical to the areas of instruments typically hidden from view (i.e., box locks). The routine use of this test will help ensure that your instrument washer is performing at a consistent level, enhancing the routine visual inspection of instruments."

The risks of residual protein

Thomas Overbey, Director of Marketing for [Ultra Clean Systems Inc.](#), points out that a growing concern in the CS/SPD is residual protein on surgical instruments.

"Protein residing on an instrument that has undergone the sterilization process poses certain risks," said Overbey. "What you thought appeared clean, and under certain testing parameters may even falsely pass as clean, can be far from it. Protein laden instruments may also trap other types of biological matter as well, and thus be rendered unclean. This deserves more attention now



Serim Research Corp's
PINNACLE Monitor for
Manual Enzymatic
Cleaning Process (MEC)

sterilization cycle parameters were met by the use of physical, chemical and biological indicators. Sterilizer printouts should be signed, chemical indicators should be visually inspected and biological indicators should be grown out to confirm spore death. Use the proper internal chemical indicator and biological indicator for your process and sterilizer cycle parameters.

Plan now for International CS Week, October 11-17, 2015

International Central Service Week recognizes the committed specialists that fill CS departments and make a difference in patient care throughout the United States.

Held annually, CS Week starts on October 11, the second Sunday of the month. The International Association Of Healthcare Central Service Materiel Management (IAHCSSM) celebrates these dedicated professionals for all of their outstanding achievements — not just this week, but each and every day of the year!

Plan your celebration now with your CS co-workers that encourages education, sharing of ideas, and appreciation for your skills and respect. And of course plan a well-deserved reward for your team for their essential role in patient safety in healthcare quality.

Visit IAHCSSM for additional ideas at

www.iahcsmm.org/events/cs-week.html

than ever from an infection perspective or even worse, prion related occurrences due to Creutzfeldt–Jakob disease (CJD) and variant Creutzfeldt–Jakob disease (vCJD).

Ultra Clean Systems' ProReveal Residual Protein Detection System uses fluorescence technology to measure the amount of, and show exactly where, protein resides on surgical instruments. The system is indicated for use just after the automatic washer disinfectant process. It collects detailed information by using individual instruments as a representation of the cleaning process. Information such as instrument type, washer and carriage level can be independently tracked. This data, over time, yields a valuable plot chart representing the cleaning efficacy of a CS/SPD."



Ultra Clean Systems' ProReveal Residual Protein Detection System

Complex devices

As surgical equipment becomes more complex, with internal components and channels that can harbor dangerous pathogens, the CS/SPD needs monitoring technology that enables them to get down into the details of the devices.

To address this issue, [Ruhof](#) offers its Test InstruSponge, an absorbent swab on a flexible wand that allows for easy maneuvering through complex internal channels of scopes and cannulated instruments to verify the presence of contaminants left after cleaning. Test InstruSponge is used in conjunction with the ATP Complete Handheld Unit and Test Swabs to give an accurate numerical measure of bioburden present.



Now that it's clean is it sterile?

Once the CS/SPD has confirmed the cleanliness of instruments, the instruments are then assembled and packaged for the next critical sterilization reprocessing step, sterilization. Monitoring the effectiveness of the sterilization process is equally important to ensuring patient safety.



Sterile every step of the way

[3M](#) offers what the company calls its "Core Four" group of products, and when used together can help assure the efficacy of the steam sterilization process. They include:

1. Equipment monitoring: The 3M Comply Bowie-Dick Plus Test Pack enables CS/SPD staff to determine whether or not their sterilizer is doing its job properly. They can use the test to monitor vacuum-assisted steam sterilizers for air leaks, inadequate air removal, inadequate steam penetration and the presence of non-condensable gases, any of which can compromise sterility.

2. Load monitoring: The 3M Attest Super Rapid 5 Steam-Plus Challenge Pack and 3M Attest Rapid 5 Steam-Plus Test Pack include biological indicators (BI) to detect the actual killing of microbial spores inside the sterilizer. If all spores die

Ruhof's Test InstruSponge

inside the BI, the CS/SPD staff members have assurance that other infectious organisms have also likely been killed inside the sterilizer. As a best practice and to provide optimal patient safety, 3M recommends that every sterilization load be monitored with a biological indicator.

3. Pack monitoring: The 3M Comply (SteriGage) Steam Chemical Integrator (AAMI Class 5) internal pack monitoring verifies that the sterilant has penetrated to the point of placement of the chemical indicator in the pack and confirms that specific exposure conditions have been met.

4. Exposure monitoring: 3M Comply Steam Indicator Tapes provide a way for sterilizer operators to know at a glance whether packs have been exposed to the sterilization process. It assures the operator handling the processed items that the pack has been exposed to the sterilization process without the need to open the pack or check Load Control records.

Sterilize faster

One way to address the need to turn around instruments faster and safer is to build efficiency into the sterilization process. [Innovative Sterilization Technologies](#) (IST) has done this with the development of its ONE TRAY terminal sterilization container, which provides significant reductions in the length of sterilization cycles from several hours to under 30 minutes. With ONE TRAY, no dry or cool time is required.

While technology can go a long way in helping the CS/SPD turn around instruments faster, Chuck Kemp, President of Customer Relations & Education for IST, stresses the critical need for staff training around both new and existing sterilization technologies.

"Our ONE TRAY terminal sterilization container is an effective new tool for hospitals handling more turnover and higher volumes of sterile processing but our technology is different than previous terminal container technologies and requires training for staff to become familiar with it," said Kemp. "Ongoing training is at the top of the list for successful sterile processing in today's changing environment. Companies like ours need to partner with facilities to ensure their products/technologies are utilized correctly at the hospital employee level. This assistance ensures the sterile processing field grows in technology while maintaining correct usage/implementation."

Tackling loaner instrumentation

According to Chuck Hughes, Vice President of Infection Prevention and Consulting Services for Cantel Medical and the lead educator for [Crosstex/SPSmedical](#), a Cantel Medical Company, loaner instrumentation presents its own specific challenges for cleaning and sterilization.

He notes how loaners routinely arrive late to the CS/SPD, in many cases without the IFU. CS/SPD staff must either delay reprocessing until they receive the IFU, or attempt to reprocess the



3M's Core Four



ONE TRAY from Innovative Sterilization Technologies

instruments without it. Hughes recommends that hospitals establish a policy for loaners and stringently enforce it by first making all instrument vendors aware, and secondly penalizing those vendors that do not comply. He points out that giving the CS/SPD enough time to reprocess complex instrument sets in advance of the scheduled surgery is the best way to ensure each device's written IFU can be followed.

To assure sterility of loaners and other instrumentation, Hughes also suggests that the CS/SPD use Class 5 integrators, which can provide an extra level of assurance when documenting the effectiveness of the sterilization cycle.

"A significant benefit of the Class 5 integrator is its ability to provide a distinct pass-or-fail result, which provides confidence to safely release routine loads in every sterilization cycle," said Hughes. "As biological indicators often run daily (and with implantable devices) and require an incubation period, the Class 5 integrator provides immediate piece of mind when used in every sterilization cycle." **HPN**

References:

1. Alfa MJ, Olson N. Comparison of Washer-Disinfecter Cleaning Indicators: Impact of Temperature and Cleaning Cycle Parameters. *American Journal of Infection Control* 2014; 42(2).



Crosstex/SPSmedical's STEAMPlus Class 5 Integrators