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Air-tight and under wraps

Sustainable sterile instrument storage and containers

by Kara Nadeau

eeping surgical instruments and supplies organized, protected from harm/contamination and easy to find is a top priority for both Central Service/Sterile Processing & Distribution (CS/SPD) and clinical teams. But it is also a significant challenge given the growing number of items needed for patient procedures, the path they must travel to and from the CS/SPD department, and space constraints faced by most healthcare organizations.

Here is the story of one CS/SPD team's efforts to transform storage for the benefit of patient care and safety, a look at instrument storage regulatory and industry guidance, and insights from storage and container vendors on products and solutions

to keep instruments protected and free of contaminants during storage and transport.

Cincinnati Children's Hospital & Medical Center storage to support growth

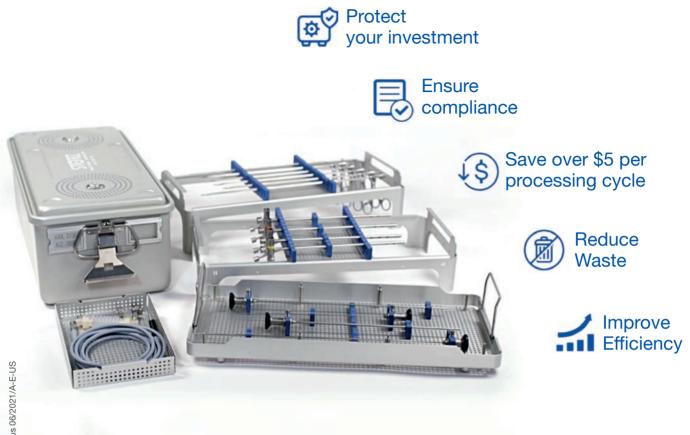
In 2019, when S. Dwayne Taylor, PA-s, CST, CFA, CRCST, CHL, CIS, CFER, ACE, SME, joined Cincinnati Children's Hospital & Medical Center as Director, Sterile Processing & Distribution, the healthcare organization was in the process of building a tower that would house a new and improved CS/SPD department. Both the main



S. Dwayne Taylor



Cincinnati Children's Hospital & Medical Center's new CS/SPD department storage area



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hospital's surgical instruments and those of select clinical areas would be stored in this new space.

"The existing sterile processing department was small, compact and cramped," said Taylor. "We are a Level 1 facility performing about 120 surgeries per day and had no room to properly store and house our sterilized instruments. It was a chronic issue where mishandling, improper storage and stacking of travs led

to downstream effects such as compression of wrapped items and holes."

Taylor called in DSI to design a storage space in the new CS/SPD department that would not just accommodate current surgical inventory but be large enough to accommodate future growth.

"DSI used CAD design and configured shelving units to help us maximize every square inch of the space," said Taylor. "They submitted several designs, and we

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selected the design we liked based on the shelving units, parameters and footprint."

In new CS/SPD storage area, each surgical specialty (e.g., orthopedic, spine, general surgery, etc.) has its own aisle for instrument and supply storage. Each cart and shelf are assigned a dedicated location that corresponds to a location within the instrument tracking system so CS/SPD team members know exactly where to go when retrieving and returning items.

Since moving into the new CS/SPD, using the DSI-designed storage configuration, and beginning a transition from wrapped trays to containers, there has been a 68% reduction in holes in wraps reported by the perioperative team. Taylor and his team have also decreased delays in delivering needed items to the operating room (OR), as he explains:

"Before the new storage configuration, we averaged 27 delays per month ranging from 30-60 minutes when looking for instruments requested by the OR. Our latest report in July 2022 showed only two delays for the month. The new space is very open, well organized, well lit, and clean, making it far easier to find items."

Taylor designated an aisle for vendor trays where each vendor has been assigned its own cart. "Vendor trays are typically a huge problem for most departments because they tend to get stuck in any crack or crevice when CS/SPD has no place to put them. The space allocated in our storage area for vendor trays has greatly helped us," he commented.

When asked for his advice to other CS/ SPD teams when renovating an existing storage space or designing/building a new one, Taylor says to always keep future growth in mind.

Storage guidance for hospitals

The Centers for Disease Control and Prevention (CDC), the Joint Commission (TJC), American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), and Centers for Medicare and Medicaid (CMS) are just a few of the organizations providing guidance to hospitals of sterile storage of instruments and supplies. Some of the key requirements and guidelines are as follows.

Temperature and humidity

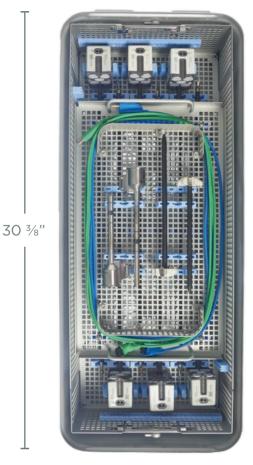
Temperature and humidity can compromise the sterility of instruments in storage by promoting microbial growth. The CDC recommends sterile storage "be a limited



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access area with a controlled temperature (may be as high as 75°F) and relative humidity (30-60% in all works areas except sterile storage, where the relative humidity should not exceed 70%)."¹

With regards to temperature and humidity of sterile storage areas, TJC² says to first ensure the hospital is compliant with all building code requirements. CMS ventilation requirements outline criteria for both new and renovated existing facilities (constructed or plans approved on or after July 5, 2016).

Ventilation

The ANSI/ASHRAE/ASHE Standard 170, Ventilation of Health Care Facilities³ provides a "mandatory minimum requirement" for health care ventilation design, including the following ventilation requirements for sterile storage in central medical and surgical supply areas:



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- Positive air pressure relationship to adjacent areas
- Minimum outdoor air exchange 2 per hour
- Minimum total air exchange 4 per hour
- Maximum relative humidity 60%
- \bullet Temperature range 72° to 78° F or 22° to 26° C

Storage conditions and monitoring

The CMS Hospital Infection Control Worksheet⁴ lists the items that a state agency must assess during an on-site survey to determine compliance with the Infection Control Condition of Participation. Areas of assessment for the storage of sterilized medical devices and instruments include:

- 3.B.15: After sterilization, medical devices and instruments are stored so that sterility is not compromised
- 3.B.16: Sterile packages are inspected for integrity and compromised packages are repackaged and reprocessed prior to use

Similarly, the CDC guidance says to store sterile items in a way that protects packaging from compromise, evaluate packages before use for loss of integrity (e.g., torn, wet, punctured), and repack and reprocess packs that are compromised.⁵

In addition to temperature, moisture and ventilation controls, the CDC says hospitals must ensure the sterile storage area provides protection against dust and insects.⁶

Sterilized item shelf life

"Safe storage times for sterile packs vary with the porosity of the wrapper and storage conditions (e.g., open versus closed cabinets)," states the CDC, noting how "any item that has been sterilized should not be used after the expiration date has been exceeded or if the sterilized package is wet, torn, or punctured."⁷

It offers the following examples for timerelated sterilization management:

- Heat-sealed, plastic peel-down pouches and wrapped packs sealed in 3-mil (3/1000 inch) polyethylene overwrap have been reported to be sterile for as long as 9 months after sterilization
- Supplies wrapped in double-thickness muslin comprising four layers, or equivalent, remain sterile for at least 30 days

The CDC goes onto note how some hospitals have switched to an event-related shelf-life practice from a time-related one, providing the following examples

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of event-related factors that contribute to product contamination: bioburden (i.e., the amount of contamination in the environment), air movement, traffic, location, humidity, insects, vermin, flooding, storage area space, open/closed shelving, temperature, and the properties of the wrap material.

As for the effectiveness of this approach, the agency cites a study where items in sterile storage were microbiology tested two years from the date of sterilization. All items were found to still be sterile. Based on research such as this, the CDC suggests "contamination of a sterile item is event-related, and the probability of contamination increases with increased handling."

Solutions for safer and more effective storage

Manufacturers are constantly innovating ways to better protect and organize instruments at each stage of their journey, including each step of processing and storage in the CS/SPD department, transport to procedural areas and use, and back to the CS/SPD space. From providing effective sterile barriers for instrument trays, to storing all sizes of supplies, here is a look at just a handful of the solutions on the market today.

Reduced touchpoints for sterile barrier protection

"While sterilization wrap offers tremendous properties to allow sterilant to enter and escape during a steam or other type of sterilization process, some products



Southwest Solutions SPD Vertical Storage System

can experience tears, cuts or holes," said Cory Ezell, North America Sales Director for Belintra, partnering with O&M HALYARD. "To greatly reduce these breaches, it's not only about having a wrap that's durable, but it's also about limiting the number of times a tray is touched or handled post sterilization."

Ezell notes how tray touchpoints are an important consideration during tray storage and transport to the OR, and points to the combined HALYARD* SMART-FOLD* Sterilization Wrap with the BELINTRA STERIYSTEM storage and transport system as a way to minimize touchpoints during these processes. He describes how it works:

"A wrapped instrument tray is placed on an enhanced shelving unit that's used to store and transport the tray during its journey to the OR. With the shelving unit on the receiving end of any touchpoints, the wrapped, sterilized instrument tray is not touched again during the transport process until it reaches the OR."

"When trays are being stored, it's also important to eliminate stacking," Ezell added. "This common practice can create more opportunities for breaches, but with the height-adjustable and spacesaving HALYARD and BELINTRA STERISYSTEM, all the wrapped packaging and soft goods necessary for one procedure can be accommodated without stacking."

Drying out microbial dangers

"Sterile items that become wet are considered contaminated because moisture brings with it microorganisms from the air and surfaces," says the CDC states in its Guideline for Disinfection and Sterilization in Healthcare Facilities (2008).⁸

The last thing anyone wants is for a surgical team to open a sterile set and find moisture. The resulting snowball effect of finding a wet pack can lead to wasted time and effort, increased workload, increased cost, potentially contaminated instruments, infection risk to the patient, poor patient outcomes, and delayed or cancellation of procedures.⁹

The potential causes of "wet packs" varies, including poor quality of wrapping materials, faulty valves of rigid container, faulty loading and packaging technique, poor steam quality, sterilizer malfunction, and design related problems in the CS/ SPD storage area.¹⁰

To help ensure the dryness of sets that undergo steam sterilization, Aesculap recently launched its AESCULAP Aicon



The HALYARD* SMART-FOLD* Sterilization Wrap with the BELINTRA STERIYSTEM storage and transport system

Sterile Container System, which offers 100% container and basket synchronization and up to 47 percent less dry time with the Enhanced Drying System (EDS).¹¹

Storage solutions large and small

A large, academic medical center performing 20,000 operative procedures per year, compared with a small, community hospital with an average surgical volume of 1,500 procedures annually will have very different requirements when it comes to surgical instrument and supply storage.

When asked for his best practices for instrument storage and surgical set storage, Craig Crock, President, Southwest Solutions Group recommends larger CS/SPD departments use automated carousel storage systems designed for the sterile core.

"Our sterile core vertical carousels for surgical kits and medical supplies save space and provide automated retrieval," said Crock. "These picking carousels hold rigid containers and surgical sets in the sterile core area. The units go tall and bring everything to an ideal ergonomic height."

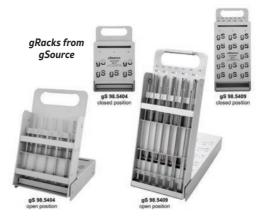
For smaller CS/SPD departments, Southwest Solutions Group offers sterile surgical instrument carts designed to reduce or eliminate perforations, tears and wet packs.

"They reduce manual handling, eliminate stacking by providing every wrapped kit with its own storage space, and safely store and transport blue wrap kits throughout the entire logistics flow," Crock added.

Small item organization

Orthopedic procedures often require wires and pins to hold bones in place, which can be challenging to manage given their small diameters. To help CS/SPD teams achieve optimal organization and convenient storage of Kirschner wires (k-wires) and bone pins, gSource offers its gRacks, with features that aid in easy access and identification

gRacks from gSource securely organize common diameter sizes of 4" and 6" k-wires (gS 98.5404) or 9" k-wires and pins (gS 98.5409). K-wires and pins are held in place when racks are closed, helping to prevent any shifting. gRacks fold close for convenient storage but convert to tabletop stands for use in the OR when open. Made in the USA from anodized aluminum, they are lightweight yet built for rigorous and repeated use; handles provide convenient



transportation. gSource K-wires and pins are sold separately. **HPN**

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