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To the average individual on the street, the topic of surgical instrument storage and containers seems like no big deal. How complicated can it really be to contain and store instruments? But for the central sterile/sterile processing department (CS/SPD) professional, the proper handling of instruments for sterilization and storage is a tremendous challenge with far reaching implications. When it is done well, the operating room (OR) has safe and effective instruments ready for use. But improper containment and storage, whether it is due to failures in process or products, can lead to instrument damage, OR delays — and most concerning — cross contamination that puts patients at risk for infection.

In this article, we examine best practices in instrument containment and storage, new products available to assist CS/SPD professionals in this area, and offer industry insights on a recent study that put rigid containers and wraps head-to-head in a sterility maintenance showdown (see sidebar).

# The right tool for the job

The first driving factor in the selection of instrument containment and storage products should be compatibility. CS/SPD staff must procure products that are approved for use with the types of sterilization methods employed by their department. They can confirm this compatibility by checking manufacturer instructions for use (IFU) to determine if the products have been validated and cleared by the Food and Drug Administration (FDA) for use with the department's modes of sterilization.

### Consider future needs

When selecting products in this area, Bas Otten, Sales Director for <u>Belintra</u>, urges CS/SPD professionals to consider not only how they support current needs but also how they will help the department improve and grow.

"The CS/SPD management should spend enough time on defining the best system for their future state-of-the-art sterile processing and storage," said Otten. "They should consider a set of components that will get them from where they stand now, into the ideal world. We recommend they lay out the entire picture before making any decisions: consider all phases in the OR — CS/SPD — storage cycle. They should always keep the AAMI and Joint Commission standards at the back of their minds and give thoughts to eventual future needs for growth or extension inside or outside the existing facility."

Belintra recently introduced its Sterisystem Logistics Flow Solution to the U.S. The solution is a sum of multiple components that can be implemented in a phased approach. It includes high quality Dry-Base instrument trays; sterilizer-proof Perfo-Safe transport baskets or transport shelves topped with a silicone mat; the UBeFlex modular storage system with its unique locations and identification plates; and open or closed transport/case carts.

#### Collaboration is critical

Many agree that interdepartmental collaboration is critical when selecting instrument containment and storage products and establishing processes that put them to proper use. This includes coordination between CS/SPD, OR staff and infection prevention.

"Halyard Health believes that in today's hospital environment it is critical to not only enforce proper maintenance and handling of sterile packaging systems (SPS), but also foster close collaboration among SPD and CS professionals, infection preventionists, surgeons and other professionals/divisions within the hospital to determine facility practices for maintaining and handling SPS to improve patient safety and reduce risk," said Lon Taylor, Director of Marketing, Surgical & Infection Prevention, Halyard Health.

"To increase efficiency, save costs and help reduce stress the OR and SPD should work together to constantly review the reprocessing cycle by evaluating instrument set organization and optimization,

and the performance of sterile packaging to support OR schedules," said Ed Nuber, Group Product Director, Central Sterile Products & Services, Aesculap Inc. "To maintain compliance and protect patient safety, the SPD and OR should work together with the infection control team to create a facility-specific verification plan based on AAMI ST79 Annex I and the manufacturer's IFU. This process serves to verify the manufacturer's sterilization validations under the surgical facility's conditions and procedures. Performance of sterile packaging is key to keeping the OR on schedule. When wrapped instrument sets are inspected in the OR and a hole is discovered, a new set must be located or the set must undergo IUSS processing. Either way, stress and cost are experienced by the OR and SPD staff."

## Supplier support

For product in-servicing and ongoing education, facilities can reach out to their solutions vendors, many of which offer helpful programs at no additional charge.

"Suppliers who are able to provide CS/SPD staff with the tools needed to achieve their department goals will be seen and depended on as a trusted partner," said Alicia Diaz, Product Manager for BD. "As a supplier, it is important to understand their needs. Providing detailed instructions for use that are easy-to-read and follow, as well as providing in-servicing when new products are introduced into the department and when new staff comes on board, is a necessary piece to the SPD efficiency puzzle."

"Every CS/SPD across the country is different with it's own set of challenges," said Ian Loper, VP of Sales & Marketing, <u>Distribution Systems International (DSI)</u>. "Workflow, stacking instruments, too much inventory and not enough space to store the inventory, managing sterility and contamination risks, the increase in Joint Commission standards, maximizing employee efficiency, safety, and productivity, and the list goes on and on.

"We here at DSI have been helping our customers tackle all of their issues-relative storage related problems," he continued. "We are LEAN specialists. Our storage experts conduct an onsite storage analysis to help design a solution around the customers needs and problems. The hospital employees stay focused on what they get paid to do while we focus on our core competencies of designing, planning, and implementing a system that will help reduce the hospital's inventory and labor costs, while increasing it's bottom line."

# Keep the bugs out

During transport and storage, there is also the risk that clean and sterilized instruments will become contaminated in the hospital environment before they reach the OR. There are a number of product innovations on the market today designed to reduce this risk through more effective barriers, easier to clean components and features to promote safer handling.

### It starts with sterilization

As Lindsay Brown, CCSVP, Clinical Educator and Sr. Sales Representative for <u>Key Surgical</u>, points out, the first step is to ensure the selected containment product facilitates effective sterilization of the instrument it contains.

"The key to organization, efficient assembly, inventory management and minimizing the risk of cross contamination is to utilize appropriate/approved containment devices as well as instrument stringers, or similar equipment used, to ensure adequate sterilant contact for medical devices assembled inside trays for sterilization," said Brown. "Suppliers are making this easier by providing many options and creating containment devices that can easily be cleaned, ones with added holes and slots to facilitate drying of the contents and also trays with small mesh compartments to help minimize the risk of lost items."



#### Key Surgical's new scope baskets

Key Surgical has developed new scope baskets designed for use in the sterilization process of rigid scopes. Constructed of durable stainless steel, the baskets feature fixed silicon brackets that help hold a rigid scope in place during sterilization and transportation. A fully-removable lid allows for easy placement of the scope in the basket. The lid slides into place on the basket and locks with an easy-to-use locking mechanism. Available in various sizes, the largest basket includes a small mesh basket to hold scope accessories. They are compatible with steam, EtO, and gas plasma sterilization.

### The case for containers

According to <u>Case Medical</u> CEO Marcia Frieze, more and more facilities are using rigid reusable containers for sterilization and storage as a substitute for single use wrapped trays. For instance, she notes that containers are being used for sterilization of endoscopic devices where disinfection might

have been used previously.

"Tears in the wrappers during transport and handling result in consequences such as OR delays, reprocessing costs and patient safety concerns when a set has been compromised," said Frieze. "Another downside is that wrapping takes more time and there is a need for extended dry times to obtain a dry load of instruments for storage and infection prevention when wrap is used versus containers. Sealed container systems provide the utmost in instrument protection. They prevent contamination from the environment as the container system itself cannot be punctured or torn like wrapped items."



Case Medical's SteriTite container system with 2D bar code

"The latest trends in instrument storage and containers includes durable, easy-to-assemble solutions that withstand and live up to the rigorous day-to-day usage," said Diaz. "Also, green initiatives have become a focus in most health care facilities. Being green eliminates waste, protects the environment and provides cost savings. Reusable rigid sterilization container systems provide the durability necessary to protect the investment of the hospital while eliminating waste that sterilization wrap can produce."

The V. Mueller brand Genesis container system now offers low temperature containers to help protect and organize heat- and moisture-sensitive surgical instrumentation during low temperature, hydrogen-peroxide sterilization. Some models are also compatible with pre-vacuum steam and 100 percent ethylene-oxide sterilization cycles. The Genesis container system consistently provides a return on investment and is a green alternative to sterilization wrap.



The V. Mueller brand Genesis container system

"The continuing trend for acute and ambulatory care centers is to move wrapped instrument sets to rigid containers, particularly for heavy orthopedic sets and delicate, sharp instruments, to protect the instruments and prevent costly reprocessing due to holes and tears in wrap," said Nuber. "Use of containers provides surgical facilities the ability to easily and consistently handle, stack, store and transport sets to and from the OR that keeps cases on schedule. Containers offer additional solutions to protect delicate and sharp instruments and optimize OR staff set up time with customizable

instrument organization systems and preconfigured trays."

It's a wrap

"There are lot of band aids for increasing effectiveness, but the real issue is care and handling," said Otten. "We notice some clear trends to comply with the AAMI standard ST 79 2013 with regards to distribution and sterile storage for the prevention of tears, cuts and holes in wrappers by avoiding stacking of the wrapped instrument sets and reducing the number of touchpoints during transport and storage."

Halyard Health and Belintra have teamed up in a co-marketing arrangement to offer sterilization packaging and logistics solutions to help protect patients from infection during surgery by ensuring the sterility of surgical instruments. By combining Halyard Health's SMART-FOLD and QUICK CHECK Sterilization Wrap with Belintra's Sterisystem Logistics Flow Solution for wrapped surgical instrument trays, the two companies will provide effective, comprehensive solutions for fulfilling surgical instrument sterility and help to improve hospitals' clinical efficiency.



Halyard Health's SMART-FOLD and QUICK CHECK Sterilization Wrap with Belintra's Sterisystem Logistics Flow Solution

Halyard's SMART-FOLD sterilization wrap features triple-layer reinforcement to protect the heaviest procedure trays and loaner sets from tears and cuts that can occur during handling. The extra reinforcement also translates to fewer trays being returned for reprocessing. Belintra's Sterisystem Solution is designed to reduce touchpoints between instrument trays. This combination of sterilization products and logistics is designed to significantly increase efficiency.

"While demands on central service departments are ever evolving, patient safety remains hospitals' number one priority," said Taylor. "In this atmosphere, it's important that suppliers provide customers with customizable, superior solutions for reducing opportunities for surgical instrument contamination, helping to ensure that sterility is maintained post-sterilization through handling and transport to the operating room. Halyard Health is continually working to identify opportunities to help our customers address challenges across healthcare delivery, including mitigating risks for healthcare-associated infections and readmissions."

Stop the stack

Whether a facility is using disposable sterilization wrap or reusable rigid containers, CS/SPD staff must ensure that the containment solution remains intact and its contents protected from potential contaminants during transport and storage.

"From our perspective we've witnessed a shift over the years in how hospitals manage and store their instruments," said Loper. "Between wrapped sets and rigid containers, the only way to ensure complete sterility is to never stack your instrumentation sets. When you stack containers on top of one another, there will be a good chance of residue build up between containers and a reduction of airflow. When you stack blue wrapped sets on top of one another or on a rigid container, this lends itself to tears of the sterile wrap."

With this issue in mind, DSI developed a LEAN storage system engineered around the need to store instrument sets with each rigid container or wrap having its own dedicated home. The storage system is ergonomically designed with employee safety in mind as well. With traditional shelving, hospital employees need to bend down and pull the heavier containers from the back of the shelf to the front. DSI's system has individual stainless steel pull out trays that allow the employee to lift the container by both handles while being in a comfortable position. Another major benefit of our LEAN high-density storage system is it allows customers to consolidate their inventory into a smaller footprint, optimize valuable floor space, and have a much better workflow within the department.

## Apply education

Products can only go so far in protecting clean and sterile instruments from contamination during transport and storage. As Diaz points out, staff education is critical to protecting patient safety. She suggests CS/SPD departments create a protocol that includes specific roles and responsibilities, stating:

"When a protocol has been established, it's clear to the staff what they are responsible for," said Diaz. "Continuous education is also an important step to keep the CS/SPD staff up-to-date on new regulations and standards. Education is also important when handling the instruments. Proper inservicing, as well as having available up-to-date instructions for use, will help the staff perform their responsibilities effectively and efficiently."

### Get organized

Keeping instrument inventory organized so that they are readily accessible when needed contributes to more efficient and effective workflow — both in the CS/SPD and OR — and helps ensure patient care is delivered in a timely and safe manner.

"We've seen the enormous increase in instrument sets in inventory," said Loper. "With more procedures taking place comes more instruments and more space required to store the containers but most CS/SPDs are running out of floor space and can't handle the required inventory levels. This creates havoc in the department as it relates to workflow, sterilization, employee safety and the operating cost for the department. With inventory often being stored in non-compliant ways employee and patient safety could be compromised."



Container Tray Storage (CTS) by Distribution Systems International

"CS/SPD should consider the efficiency, ease of use, ergonomics, time savings and cleanliness of an instrument storage solution," said David M. Phillips, Marketing Manager, <u>Hänel Storage Systems</u>. "The best option should deliver surgical instruments when surgeons need them, keep surgeries on schedule and allow employees to do their jobs faster and safer. Sterile supplies should be moved around as little as possible, so infection rates can be kept low."

The Hänel Rotomat is a vertical storage carousel that saves time, space, costs and the physical health of employees. The Rotomat allows surgical trays, instruments and supplies to be ergonomically accessed where lifting them takes the least amount of effort. Its compact footprint enables up to 80 percent more storage capacity by making use of available room height, compared to static shelving. Supplies can be kept centrally located, permitting more efficient delivery to the OR and eliminating the need to search countless carts. Hänel's easy-to-use inventory management can improve accuracy to over 99 percent, leading to a significant time savings.



The Hänel Rotomat vertical storage carousel

To facilitate effective instrument organization, Case Medical offers customized tray solutions. According to Frieze, the company has a database of numerous instrument sets regularly used in healthcare facilities, which can be ordered pre-assembled. It also offers patented modular inserts that can be used and reconfigured for instrument organization.

"Organized instrument sets not only facilitate the instrument count process and contribute to safer and quicker reprocessing, but importantly contribute to the bottom line by preventing damage to devices that can be very costly to repair or replace," said Frieze.

Case Medical also offers a solution called CaseTrak 360 to manage instrument inventory, provide real time tracking, prompts and assembly instructions. This software program helps CS/SPD professionals coordinate their schedule and needs, track instrument sets from the OR to SPD in real time and go paperless using a 2D barcode with set information, prompts and IFUs that can be etched onto a permanent label or directly onto the tray.

"Suppliers that provide a variety of instrument organization products, as well as services that optimize, maintain and repair instrument sets, can add significant value," said Nuber.

Aesculap addresses real world OR and CS/SPD challenges through its Surgical Asset Management program, Repair Services and Sterilization Products. These products and services improve efficiency by:



#### Aesculap's SterilContainer System

- Minimizing redundant, unneeded instruments: Through set standardization and optimization,
   Aesculap can help facilities reduce unnecessary reprocessing and potentially minimize its number of sets, while assuring the instruments within the set are correct and easily accessed.
- Protecting sets in well organized rigid sterilization containers: which can increase ease of finding
  and presenting needed instruments during surgery and can extend the life of the instruments while
  reducing time and cost of repairing and replacing damaged equipment.
- Repairing and properly maintaining needed instruments: potentially minimizing wasted time and resources due to dull or unusable instruments that could delay surgical procedures.

# Protect your assets

Hospitals spend hundreds of thousands of dollars on surgical instruments. They are a critical and costly resource that must be protected from damage and loss. Instrument repairs mean not only added costs to a facility but also inventory that is unavailable to the OR however long the repair takes.

"Healthcare facilities are paying closer attention to methods that will help reduce the risk of increased

repair costs due to inadequate containment devices used or lack instrument protection inside containment devices," said Brown. "Using accessories like tray liners or silicone finger mats inside containers such as mesh trays help not only protect the instrument from damage during storage and transportation but also allow the techs handling the instruments to protect themselves from sharps injuries. Containment options also allow SPD and OR techs to keep better track of small pieces of medical equipment, such as clips and screws."

And it's not just the instruments. The containers themselves must also be properly used and maintained. Brown urges CS/SPD staff to make sure their department has detailed IFUs for all containment devices to ensure proper sterilization of the contents used within. She says all risks should be assessed as well, stating:

"For instance, in the case of rigid container use, gaskets will eventually need to be replaced when cracked or worn. Often times inspection of this area is forgotten, which could pose a risk for cross-contamination."

According to Frieze, not all container systems are the same. When selecting containers, she says it is important that a facility purchases something truly reusable that will last over time without unnecessary repair.

"Always acquaint yourself with the IFUs and ensure the product can be continuously reprocessed and that the reprocessing instructions are followed and meet current guidelines," said Frieze. "As most container systems are manufactured from anodized aluminum, it is important to use a pH neutral cleaner to maintain the integrity of the material."

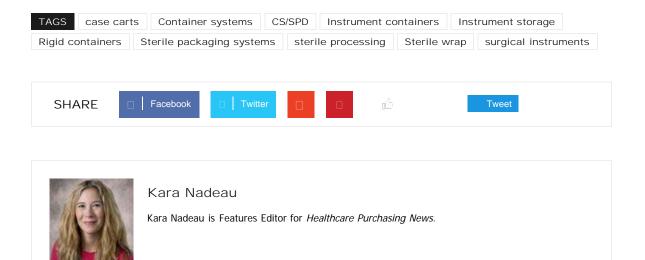
### Label it

"Determining the status of instruments while being transported between departments can be challenging if they aren't properly labeled and identified," said Matthew Smith, Marketing Manager for <a href="Healthmark">Healthmark</a>. "Communication by labeling is a key factor in ensuring surgical instruments are safe for use when being stored and transported."

Designed for compliance with OSHA standard CFR 1910.1030 the Healthmark Transportation Identification Tag is 3.125" x 5.125" with one perforated tab, a green top tab with "CLEAN" in black text, a fluorescent orange/red bottom tab with "DIRTY" in black text, and the removable OSHA

approved "Biohazard Label" adhesive backing. The tag is produced precisely for transporting materials considered a biohazard, while acting as an essential communication tool in the process. By labeling a cart or container "biohazard" upon its return to the sterile processing department, the tag assists in supplying information to the OR/Procedure Room. Furthermore it has a checklist for the surgical/procedure room/sterile processing team to ensure adequate delivery of the case cart or container in question.

See the sidebar: Wrap vs. containers study prompts dialogue, questions among industry thought leaders



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