

IMPLEMENTATION MODULE:

Rigid Sterilization Containers in the OR

The operating room generates a large volume of disposable plastics, ranging from single-use medical devices to packaging to sterile wrap to plastic pour bottles for irrigation. The vast majority of these items go out the door as waste—either with regulated medical waste (where comprehensive segregation efforts have not yet been undertaken) or as solid waste or recycling. More efficient than disposing of waste in the least impactful way is preventing generation of waste altogether, and evaluating the potential to transition some items from disposable to reusable while still ensuring infection prevention and protection patient safety. In addition to generating less material altogether, other benefits of reusables include reduced labor and time for waste management and transport. Disposable blue sterile wrap, used for the one-time sterilization of instruments before surgery, comprises a large portion of surgical waste—estimated by one study to comprise 19% of the OR waste stream.¹ A recent onsite hospital study found that blue wrap may make up as much as 55% of the total volume of disposable plastics leaving the OR.² Blue sterile wrap is a soft plastic, made of polypropylene or #5 plastic.

While polypropylene blue wrap is ubiquitous in hospitals, staff often have problems with breakthrough, where sharp instruments or tray corners push through the blue wrap, forcing the materials inside to be re-sterilized. At Mills-Peninsula Medical Center, Central Processing estimated 5-10 torn blue wrap sets per week at a cost of \$100/set—costing the organization between \$500-\$1000 per week and up to \$50,000 annually,³ just from repackaging and resterilization efforts. Indicator systems are used to ensure sterility for items sterilized with blue wrap. Most hospitals use an indicator tape in concert with the blue wrap to validate sterility. While alternatives are available on the market, many hospitals use an indicator tape containing a lead salt. Lead is considered a hazardous waste by the US Environmental Protection Agency when found in certain concentrations, and

must be disposed of using a set of stringent management practices and can be very cost-prohibitive. In order to meet environmental compliance obligations, hospitals using lead indicator tape should be collecting it for proper disposal. This indicator tape can also be a contaminant in instances where the hospital has been able to develop a recycling program for blue wrap.

While sterilization wrap will continue to be used to some degree, hospitals are seeking ways to improve upon the current process, reduce resterilization needs, reduce the use of disposable or single-use products and reduce waste. One attractive option is the use of rigid sterilization containers for reusable medical instruments requiring sterilization. Sterilization packaging must allow for sterilant penetration during the sterilization process, prevent microbial penetration during storage and transport as a means of maintaining sterility of processed items, and facilitate aseptic presentation of the contents.⁴ Rigid containers (also called reusable hard cases) are typically made of anodized aluminum or stainless steel, can require a filter or be filterless, and meet all of these criteria. Additionally, rigid containers can protect the instruments from inadvertent drops, can facilitate the organization of the instrument sets and are not subject to any of the breakthrough or resterilization issues prevalent with blue wrap. Other noted benefits include a potential reduction in ergonomic wrapping injuries for Sterile Processing Department (SPD) staff, increased ease in keeping track of instruments, the avoided cost of blue sterile wrap and of course, the waste reduction benefits in the OR.

There are several standards that regulate and oversee the use of sterilization containers—whether hard cases or wrapped trays. Both are considered Class II medical devices by the FDA and approved as such.

The Association of Perioperative Registered Nurses' (AORN) **Recommended Practice (RP) for Selection and Use of Packaging Systems for Sterilization** states that *"Packaging systems should be evaluated before purchase and used to ensure that items to be packaged can be sterilized by the specific sterilizers and or sterilization methods to be used and should be compatible with the specific sterilization process for which it is designed."*^{5,6} The association for the Advancement of Medical Instrumentation (ANSI/AAMI) **Standard 79, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities** reiterates that health care personnel bear the ultimate responsibility to ensure that a packaging system is suitable for use in sterilization processing and sterility maintenance.⁷

A transition to rigid sterilization containers can make long-term financial sense for a healthcare organization. While these containers do have an upfront cost, many hospitals find that payback can be less than a year if the organization is tracking all of the financial benefits. A set of simple cost-benefit factors might look like this:

Blue Sterile Wrap	Rigid Sterilization Containers
Purchase Cost of Sterilization Wrap (per surgery)	Purchase Cost of Rigid Containers
Purchase Cost of Indicator Tape	Purchase Cost of Filters (per surgery if applicable)
Cost of Rewrapping Torn Sets	Continued Purchase of Sterilization Wrap (for limited number of surgeries where rigid containers are not yet appropriate and wrapping must continue)
Waste Disposal Costs of Blue Wrap (as RMW, solid waste or recycling)	--
Waste Disposal Costs of Indicator Tape (if lead indicator tape then hazardous waste)	--
Total Cost of Using Sterilization Wrap	Total Cost of Using Rigid Containers

This does not factor in labor costs—for wrapping and rewrapping sets in sterilization wrap and the waste handling related to blue wrap disposal on the one side and to clean the rigid containers and replace the filters on the other side. One could argue, however, that just outlining the tasks associated with each points to a benefit in going with the reusable hard cases.

How then does a facility make the case to transition to rigid sterilization containers for surgical instrumentation, and operationalize the change? There are several finite steps an organization can follow to make a move to reusable hard cases in the OR.

Step 1: Identify the Project Team

A transition to rigid sterilization containers requires collaboration among the SPD, the OR, Infection Prevention and Purchasing. Put together a small project team that can work together to answer all of the questions about a transition to rigid containers and support the project from concept to implementation. The team will need to think about everything from existing costs, the business case, the selection of containers to storage space to appropriate sterilization procedures to front-end cost as well as costs for existing sterilization procedures for comparison.

Step 2: Develop a Baseline to Support Cost-Benefit Analysis

Before asking the organization to invest in reusable hard cases for the OR, it will be important to be able to demonstrate what the current practice of utilizing blue sterile wrap is costing the organization. Work with the project team to develop baseline costs for each of the following items:

- Determine the current supply costs for purchasing blue wrap and indicator tape for the OR.** Work with Purchasing to determine the exact volumes and costs of blue wrap and indicator tape ordered for the OR and utilized over a set period—such as the past year.
- Determine the volume of blue wrap purchased for the OR.** Use purchasing records to determine how many units were purchased. Utilize the shipped weight information or actually weigh the various shipped packages to determine exact weight. Multiply by total number of units for an estimated total weight. Remember to exclude packaging weight and that different sized blue wrap will weigh different amounts.
- Determine how the majority of blue wrap is currently being disposed of in the OR.** Is waste in the OR carefully segregated or is most of the waste going into regulated medical waste containers? Does the hospital have a program to recycle medical plastics yet? Does the program include blue wrap?
- Determine current costs for disposing of blue wrap in the OR.** Reach out to Environmental Services (EVS) to determine what the organization is paying per pound for the disposal of whichever waste stream blue wrap is currently being disposed in. Multiply the cost per pound by the total weight of blue wrap being purchased to determine total waste costs for blue wrap disposal.



Many hospitals are beginning to transfer large percentages of their surgical instrumentation into rigid sterilization containers.

- **Determine current costs for disposing of lead indicator tape (if applicable) in the OR.** Work with SPD to estimate the amount of indicator tape used by the OR. Weigh the indicator tape to determine weight per roll and multiply to get the total weight of indicator tape used by the OR. Indicator tape containing lead must be handled as hazardous waste. Check with EVS to determine pricing for hazardous waste per pound. Multiply by total indicator tape weight to determine total waste disposal costs for indicator tape in the OR. Note: If the facility is not using lead indicator tape, this step may be skipped for expedience as cost of indicator tape disposal in other waste streams will be negligible.
- **Determine how many OR packs each week need to be rewrapped due to torn blue wrap.** Collaborate with SPD to determine a conservative estimate for how many packs are sent back to SPD from the OR each week to be rewrapped and sterilized as a result of breakthrough or torn wrap. Multiply across the year to determine an estimate for the number of packs that require rewrapping and resterilization.
- **Determine how much the organization is spending to rewrap torn kits or packs for the OR.** SPD in concert with Purchasing should be able to determine how much is being spent on rewrapping packs in terms of additional blue wrap supply costs. If sterilization costs or labor costs are available, factor those in. Multiply across the year for total expenditure.

Add up the costs to demonstrate what the OR is currently spending yearly to utilize blue sterilization wrap. This figure will then be matched up against the front end cost of rigid sterilization containers to determine the payback period and an accurate return on investment (ROI).

Step 3: Evaluate Rigid Sterilization Containers

Work with the project team to evaluate different vendors for rigid sterilization containers. Reach out to the organization's Group Purchasing Organization (GPO) to see which suppliers may be recommended and available on contract. Ask colleagues within professional associations which manufacturer they have had success with. The team should determine the number and kinds of rigid containers needed to transition from blue wrap to hard cases for sterilization. Evaluate different options for reusable hard cases. There are a number of factors that will play a role in which container the organization chooses. Some key factors include:

- **What material is the container made of? Is it resistant to corrosion?**
- **How easy are the containers to use and clean?**
- **What is the estimated life of the container?**
- **What kind of containers does the organization need?** Different kits will require different sized containers, and packs with many small items may need particular accessories to prevent part loss or disorganization.
- **How much do the containers weigh when filled with contents?** A maximum weight limit of 25 pounds for containerized instrument sets has been recommended in the new ANSI/AAMI ST77:2006 Standard, Containment Devices for Reusable Medical Device Sterilization.⁸ The requirement was designed to ensure that the contents of the container can be reliably sterilized and dried.⁹
- **Does the container utilize a filter system or is it filterless?** There are some ongoing costs tied to containers with filter systems and filters need to be checked for integrity before each case. One study demonstrated that filterless systems have less potential for microbial penetration than the filtered systems,¹⁰ but additional research is unavailable.
- **Are the containers compatible with the organization's existing sterilization equipment?** Some containers are intended to be used only with steam sterilization. Some containers are not intended for use with low temperature sterilization techniques or appropriate for lumened devices.¹¹ Some containers can be used in both systems but be sure to check whether containers can withstand flash sterilization. It is very important to ensure compatibility early on in the evaluation process. Additionally, ensure that the containers are able to fit into different sterilization equipment.

- **Do the containers provide aseptic presentation of the contents?** Independent hospital verification that the containers meet the manufacturer's claims is critically important. It is recommended to test the container with the maximum load recommended by the manufacturer utilizing biological and chemical indicators in hard to reach corners of the tray to ensure efficacy of the container. Work with Infection Prevention and SPD to ensure appropriate testing.
- **How much do the containers cost?** Work with Purchasing to get an accurate cost assessment. Vendors should be able to provide the organization with an accurate price quote as well as determine any volume discounts or GPO rebates. Manufacturers can also work with the organization to determine the benefits of phasing in container purchase versus purchasing them in a lump sum.
- **What other hospitals are using a particular company's containers?** Ask for a list of customers and reach out to get the user's perspective and lessons learned from transitioning to reusables.

Step 4: Consider Storage and Placement

Once rigid sterilization containers have been evaluated, it is critical for the project team to determine appropriate storage for the new containers. Hard cases can take up more room than blue-wrapped packs and supply room adjustments may need to be made. Work with SPD to determine the most appropriate placement and storage locations for the new containers. Additionally, consideration should be given to the weight of different containers when full of instruments. While AAMI recommends a maximum load of 25 pounds, ensuring that heavier equipment is located lower on shelving will reduce the risk of ergonomic injuries for staff.

Step 5: Presenting the Case for Reusable Sterilization Containers

Once the organization has determined an appropriate vendor and accurate cost information and has tackled the storage issue, it is time to present the case to leadership for approval of funds. Using the baseline costs developed in Step 2, present OR management and leadership the estimated payback and ROI for the rigid sterilization containers. Be sure to include aspects of the transition that may increase efficiency or reduce wait time in the OR. Depending on the financial resources of the organization, reusable containers may be purchased in one lump sum, or may need to be phased in over time and as resources allow. If so, look at the kinds of cases that get performed most often and prioritize the selection of rigid sterilization containers for those kinds of cases/equipment. This can lead to the greatest savings over the shortest period.



Rigid containers share supply shelf space with blue wrapped kits.

Step 6: Educate Staff

When the containers arrive for use, staff in both SPD and the OR will need to be properly trained on how to utilize the new container system. Sterile Processing staff will need the most detailed training. Some considerations for SPD staff include learning the specifics on proper cleaning for the containers—some systems require a pH neutral detergent to maintain the passive layer and the durability of the container;¹² appropriate filter replacement procedures and checks on locks and gaskets. Appropriate placement in sterilization equipment is also important—sterilization containers should be placed on lower shelves when sharing space with blue wrapped packs to ensure condensate doesn't drip onto sterilized packs and SPD staff should note that some containers should not be stacked unless containers are of the same brand and specifically allowed by the manufacturer. OR staff will need to be trained to inspect the external latch, filters, valves and tamper-evident devices (locks). The lid should also be inspected for integrity of the filter or valve and the gasket.¹³ If using a disposable filter model, staff will want to keep apprised of common missteps that can occur with filter replacement and lock mechanisms.

OR Staff will also need to get used to using the rigid containers in the OR including how they make their way into and perhaps more importantly—out of—the OR. In-Services for both departments will be a valuable starting point. Seize any missteps or lack of comprehension as an opportunity for retraining. Infection prevention is absolutely paramount and ensuring items are sterile at time of use and that the container ensures the integrity of the sterilized contents until ready for use is of the utmost importance. Proper training and education can ensure safe and appropriate handling procedures. Developing a policy to support the proper cleaning, inspection and handling of containers can also build the proper procedures into the fabric of the organization. And adding appropriate training on rigid container for annual staff training and for all new hires is also a smart idea.

Step 7: Special Circumstances

Ensure that SPD staff in particular is aware of some of the special handling required for steam sterilization versus low temperature sterilization versus flash sterilization.¹⁴ For steam sterilization, wet packs are not acceptable and all items need to be dry before sterilization.¹⁵ Oxidative sterilants such as hydrogen peroxide or ozone, for example, require non-cellulose filters.¹⁶ New scrutiny is being placed on flash sterilization procedures with organizations including AORN, AAMI, the Joint Commission, the Centers for Disease Control and Prevention, and the Association for Professionals in Infection Control and Epidemiology (APIC) all taking a closer look at how flash sterilization procedures may be linked to surgical site infections. These same organizations are also exploring both the prevalence and practice of flash sterilization.¹⁷ Hospitals need to make sure they are up to speed on the latest guidance from these organizations on appropriate uses of flash sterilization. AORN, for example, clearly recommends that “Rigid sterilization containers designed and intended for flash-sterilization cycles should be used.”¹⁸

Step 8: Track Savings Data and Demonstrate Payback

Work with the project team to keep a running tally of avoided costs relative to the reduction or elimination of the use of blue sterilization wrap. Also note any increases in efficiency that come as a result of the transition—less prep time in SPD, less set-up time in the OR, etc. While not easy to generate cost-savings data from these efficiencies, sharing the improvements—even anecdotally—will be helpful for leadership. Keep the OR management apprised of all avoided costs and ensure they are aware when the containers have demonstrated payback. Validating a strong ROI with good data can also help build management’s trust—perhaps making it easier to approach them for the next greening project in the OR.

Step 9: Improve Process and Celebrate Success!

Check in with staff in both the OR and SPD to ensure things are running smoothly. Every new product transition is a work in progress, and takes some getting used to. Asking staff if they have concerns they would like to share may yield more results than expecting the same staff to step forward and complain about the new process. In addition, it can be used to demonstrate to the staff that management takes their concerns seriously and will work to address any issues that may arise. Work with Purchasing to consider if the organization can require vendors to supply their own rigid cases, especially on equipment used on consignment. Often this feature can be built into the contract language, with a little leverage. Share the updates on financial savings with the staff along with the environmental benefits of the transition. Every member of the OR and SPD staff played a role in ensuring the transition would work. Acknowledge their contributions and celebrate success.

For More Information: Go to www.GreeningTheOR.org for a list of key resources that can assist you in this program area. Because this list is updated often, we keep it online, so as not to date this implementation module. Also available are case studies on the transition to rigid sterilization containers in the OR. Learn from your peers!

Endnotes

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