

March 2006

The self-study lesson on this central service topic was developed by STERIS and AAMI (Association for the Advancement of Medical Instrumentation). The lessons are administered by KSR.

## Earn CEUs

The series can assist readers in maintaining their CS certification. After careful study of the lesson, complete the examination at the end of this section. Mail the complete examination and scoring fee to Healthcare Purchasing News for grading. We will notify you if you have a passing score of 70 percent or higher, and you will receive a certificate of completion within 30 days. Previous lessons are available on the Internet at [www.hponline.com](http://www.hponline.com).

## Certification

This in-service has been pre-approved by the CBSPD to be used once during an individual's re-certification period, for 1 contact hour. The approval is good for 5 years from the original publication date. Refer to the CBSPD Continuing Education Protocols for submitting a pre-approved in-service at re-certification time. Protocols can be found at CBSPD website [sterileprocessing.org](http://sterileprocessing.org) or by calling CBSPD office at 908-788-3847.

## Learning objectives

1. Discuss the importance of routine inspection and maintenance of rigid sterilization containers.
2. List all the components and functional elements that are critical to the proper operation of a rigid sterilization container system.
3. Describe the function, inspection and maintenance of rigid container gaskets, valves, filters and latches.
4. Explain why rigid containers may require repairs and who should perform them.
5. List the cost factors to consider when choosing a rigid container system.

## For more information

Direct any questions to Healthcare Purchasing News (941) 927-9345, ext.202.

### THIS MONTH SPONSORED BY:

STERIS



and

AAMI  
ASSOCIATION FOR THE ADVANCEMENT  
OF MEDICAL INSTRUMENTATION



## Routine inspection and repair of rigid sterilization containers

by Linda Clement, BSM, CRCST; Michael E. Russell, RN, MSN, CNS; John Wheeler, RN, BSN, MBA, CNOR

After a time-consuming justification and budgeting process, you have finally made your first purchase of rigid sterilization containers. The containers arrive in a sea of shipping cartons, which you carefully unpack and decontaminate. You begin setting up trays for sterilization and are now off and running with your new process to contain and sterilize instrument sets. The days of holes in disposable sterilization wrap and being scorned by O.R. staff and surgeons because of compromised packaging will soon be a distant memory. Dragging an instrument set on and off a sterilization cart or supply storage shelf no longer generates a second thought. It may appear that life is now easy and good, but this false sense of security can be problematic when using rigid sterilization containers in a healthcare facility.

Sterility maintenance is an issue with any type of packaging material. Whether you use peel pouches, disposable or reusable sterilization wrap, or rigid sterilization containers, they all require proper use, handling, and inspection to ensure that the package integrity has not been compromised before it is opened for use.

Each rigid sterilization container manufacturer has specific inspection and repair instructions that must be stringently followed in order to ensure that the container system is functioning optimally. Although some users of rigid containers may not be aware of the need to inspect containers before each use, or they may not consider inspection to be important, it is an absolutely essential step in assuring sterility maintenance.

### Policies

Sterilization container manufacturers are responsible for providing customers with instructions for use, inspection and maintenance, including the recommended frequency with which components should be replaced. It is absolutely essential that the container manufacturer's instructions for use be thoroughly read before the containers are put into use.

In addition, departmental policies and procedures should be written and implemented to ensure that the manufacturer's guidelines are adhered to and that the Association for the Advancement of Medical Instrumentation (AAMI) recommended practice standards are followed. As with all policies and procedures, they should

also be reviewed by the appropriate facility committee members and written to emphasize patient care and minimize any potential for medical liability.

### Inspection

Container components should be inspected thoroughly when they are first received from the manufacturer. Once they are placed into service, routine inspection should be conducted between uses, and a thorough annual audit should be conducted to identify problems that may be overlooked during routine inspection.

### Gaskets

Gaskets or seals are an often-neglected component of a rigid sterilization container. These components are extremely important in ensuring that the container base and lid properly seat together, providing an airtight seal to assist in maintaining sterility of the container contents after sterilization. Some gaskets are more pliable than others. Some are solid type gaskets, while others are hollow. Regardless of the type of gasket, each must be meticulously inspected before each use for fraying, cuts, missing pieces, bubbling, and excessive compression. If a gasket or seal is excessively compressed, the latch will not be able to hold the lid securely in place, which may result in a latch disengaging during handling or transport. Users must be aware of any manufacturer recommendations for routine replacement of gaskets or seals. A mechanism for tracking gasket replacement should be in place.

### Valves

Some rigid sterilization container systems use valve-type closures rather than filters. The valves may require removal, disassembly and cleaning, and it is important to follow the manufacturer's instructions regarding the frequency of performing these tasks. Valves must be open during sterilization to provide a portal for steam penetration of the container contents. Valves must also remain open for water vapor to escape prior to drying and cooling. If valves close prematurely, moisture may not be adequately eliminated and there may be moisture in the container when it is opened for use. In addition, sterilant penetration may be interfered with if the valves are not properly maintained.

The microbial barrier may be compromised, which can cause the contents to become contaminated.

### Interior baskets

Like other components of rigid sterilization containers, interior baskets must also be inspected before each use. Handles that do not function properly can potentially interfere with aseptic removal from the container at the point of use. Baskets comprised of woven heavy gauge wire may break if handled improperly, resulting in small broken wires that can tear sterile field barriers or sterile gloves during handling. Broken handles and basket wires should be repaired or replaced immediately.

Dividers, organizing pins, and organizing cases should also be inspected to ensure that they are not loose and are in good repair. Container or accessory screws, rivets, nuts, and bolts must also be securely in place.

### Container mating surfaces

The container mating surfaces must be carefully

inspected to ensure that the lid and container bottom fit together correctly and securely to maintain a microbial barrier. Dents, chips, splintering, burs, and cracks can all affect sterility maintenance and should be repaired. Dented container surfaces that affect mating surfaces must be treated no differently than a hole or tear in a wrapped package or peel pouch.

Both internal and external container surfaces must also be inspected for pitting and other damage that may have been caused by the use of improper and potentially harmful chemicals for cleaning and disinfection.

### Filters and latches

The filter retention mechanism function is essential for holding both disposable and reusable filters in place. Retention mechanism springs, screws and rivets should be in good working order and should hold filter material securely and uniformly. Filter retention mechanisms must also be able to withstand vibrations and stay in place during handling and transport. If offsite transport is a factor, it may pose additional challenges to maintaining a container's function as a unit.

Some container system filters and retention plates may not be interchangeable in all lids and bases. Attention must be given to ensuring that the appropriate filter retention mechanism and correct filters are used together.

Some container systems have reusable filters or filter options and must be carefully examined

for integrity before use. Filters that are cracked or chipped must be replaced, and reusable filter material should not be used beyond the recommended useful life specified by the manufacturer.

Only the disposable or reusable filters that have been tested and documented to be efficacious in your specific container system should be used. Whether they are disposable or reusable, filters should be inspected for visible damage or holes before use. Furthermore, using unapproved filters or filter materials can affect the sterilization process by inhibiting air removal or sterilant penetration and evacuation, even if you think you have "tested" them in your containers. The kind of filter material testing that is conducted by container manufacturers cannot be duplicated in the healthcare setting and should not be attempted by users.

Latches must secure the lid to the container base without disengaging unexpectedly. Spring mechanisms should be functioning properly and the latch surfaces must not be distorted.

### Repair

Before purchasing a rigid sterilization container system it is important to understand the associated costs of maintenance and anticipated repairs of those units. Some container systems are much more durable than others and some have more components than others. It is also important to know the estimated or expected useful life of the container and each of its components. For cost containment purposes, purchasers should also review the container system warranties and preventive maintenance requirements (e.g. frequency, methods for tracking preventive maintenance activities, and the associated expenses).

The manufacturer should provide guidance for repair, parts replacement and parts availability, to assist container owners in securing acceptable and competent resources for these types of services.

When rigid sterilization containers or their components need to be repaired, healthcare facilities handle repairs in a variety of ways: con-

tainers are returned to the manufacturer for repair, they are repaired by mobile instrument repair services, or they are sometimes repaired within the facility by a department staff member or the hospital maintenance department.

We can certainly empathize with a facility wanting to take the path of convenience, speed, and economy for repairing their containers. However, the seemingly endless stacks of broken, dented, and mangled containers in some hospitals' container "bone yards" makes it clear that short-term economic considerations should not be the sole factor used to choose a repair source.

It is also important to note that rigid sterilization containers are Class II Medical Devices subject to Food and Drug Administration regulatory requirements; therefore, unauthorized modification or repair should be avoided.

### Conclusion

In order to preserve the integrity of a rigid sterilization container system, thorough and routine inspections of the system and its individual components must be completed following the manufacturer's instructions and the facility's written procedures. Routine inspection and maintenance ensures proper function that allows air removal, sterilant penetration and the ability to inhibit microbial migration and contamination. All of the container's components must function effectively as a unit, and only proper use, inspection and maintenance can assure that this is accomplished. These activities are essential components of any healthcare facility's quality assurance program. **HPN**

*Linda Clement, BSM, CRCST; is consulting manager for STERIS Corporation. Michael E. Russell, RN, MSN; CNS; and John Wheeler, RN, BSN, MBA, CNOR; are clinical education specialists for STERIS Corporation.*

Reference:  
Association for the Advancement of Medical Instrumentation, *Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities*, 2nd edition. ANSI/AAMI ST33:1996. Arlington (VA): AAMI, 1996. American National Standard.

See **SELF-STUDY SERIES** on page 34

- Answers
1. D
  2. B
  3. B
  4. C
  5. B
  6. A
  7. D
  8. D
  9. D
  10. D



Container filter media must be inspected for integrity and proper placement.



Container lids must be inspected for dents and chips.

Continuing Education Test-March 2006

# Routine inspection and repair of rigid sterilization containers

**CIRCLE THE CORRECT ANSWER**

1. Rigid container systems are virtually maintenance-free and ready to use without concern
  - a) True
  - b) False
2. Inspection of the rigid container includes:
  - a) Check to see that lid and container surfaces mate properly
  - b) Inspect gaskets for fraying, cuts, missing pieces, bubbling and excessive compression
  - c) Ensure that filter retention mechanisms are in good working order
  - d) Ensure that latches secure the lid without disengaging
  - e) All of the above
3. Rigid sterilization containers may be repaired by any reputable surgical instrument repair service.
  - a) True
  - b) False
4. The greatest problem with broken handles on interior baskets is they:
  - a) Just look bad
  - b) Snag linen in the set
  - c) Interfere with aseptic removal from the container
5. Rigid container gaskets or seals should be:
  - a) Hollow only
  - b) Inspected for cuts, tears, bubbling and fraying
  - c) Replaced annually
  - d) Compressed to allow the lid to fit loosely on the container base
6. Some rigid containers may employ valves instead of filters
  - a) True
  - b) False
7. Pitting is:
  - a) Caused by retained water
  - b) Damage by improper and potentially harmful chemicals
  - c) Not a problem since it only affects the looks of the container
8. Valves must remain open during sterilization to:
  - a) Allow steam to penetrate the container
  - b) Provide a route to remove air from the container
  - c) Allow water vapor to escape prior to drying and cooling
  - d) All of the above
9. Filters:
  - a) May be reusable or disposable
  - b) Must be inspected for holes, tears, chips or cracks
  - c) Be properly retained to be effective
  - d) All of the above
10. Policies addressing rigid container should be written to:
  - a) Address AAMI standards
  - b) Ensure that manufacturer's guidelines are adhered to
  - c) Provide legal guidance for the facility
  - d) All of the above

**Request for scoring**

**March 2006**

Presented by

**HEALTHCARE Purchasing NEWS.**  
Sponsored by **STERIS**

- I have enclosed the scoring fee of \$10. (Please make checks payable to **KSR Publishing, Inc.** We regret that no refunds can be given.)
- Detach exam, fold and return to:**  
Continuing Education Division  
KSR Publishing, Inc.  
2477 Stickney Point Road, Ste. 315B  
Sarasota, FL 34231  
PH: 941-927-9345 Fax: 941-927-9588

Please print or type. Return this page only.

Name	Title
Hospital Name	(            )
Mailing address/P.O. box	Daytime telephone
City	Apt./Suite
	State
	Zip code