Standard Operating Procedure

Rigid instrument Containers General Care and Use

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OBJECTIVES

- Identify the general description and purpose of rigid containers.
- Identify the basic structure and anatomy of rigid container systems.
- Identify the decontamination process for rigid container systems.
- Identify the assembly, inspection, sterilizer loading processes and storage requirements for rigid container systems.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary) working within Medical Device Reprocessing.

ELEMENTS

1. Description & purpose
   - 1.1 Rigid, reusable container systems provide an efficient, cost-effective way to package and protect reusable medical devices for sterilization, transport and storage.
   - 1.2 Rigid containers are typically made of anodized aluminum
   - 1.3 Materials used for rigid container systems shall:
     - a) Be appropriate for the devices(s) being sterilized
     - b) Allow for adequate air removal, sterilant penetration, and evacuation
     - c) Be a barrier to micro-organisms, dust, and vermin
     - d) Be stable under sterilization conditions
     - e) Be strong enough to withstand normal handling; and
     - f) Allow for aseptic removal of the sterilized medical devices(s)
   - 1.4 There are two standard designs of reusable rigid containers including:
     - a) Sealable containers systems with multiple components that maintain sterility of lightweight anodized aluminum) and
     - b) Containers designed to be wrapped (plastic or metal or a combination thereof)

For more information contact
ipc.mdrreviews@ahs.ca

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Note: This procedure addresses rigid instrument container systems that provide a sealed system for medical devices before, during and after sterilization without the use of an outer textile wrapper.

1.5 Container Systems are available for use with steam sterilization and/or low temperature sterilization methods.

2. Basic anatomy and structure

2.1 Rigid container systems typically include but are **not** limited to the following components:

a) Box-like base
b) Removable lid with gasket
c) Reusable or disposable filter(s) and filter retaining plate(s)
d) Latching mechanisms
e) Disposable tamper-evident locking devices
f) Handles
g) Disposable data card
h) Set/device identification labels or tags
i) Instrument basket(s) with validated accessories which may include: instrument brackets, partitions, dividers, posts, pins, clips, nuts and washers.

- **Note**: Some container systems are designed with a filter-less system equipped with a pressure sensitive or thermostatic valve which opens and closes within the sterilizer.

3. Decontamination

3.1 Always follow the validated Manufacturer's Instructions for Use (MIFU) for the decontamination of all devices, equipment and supplies.

3.2 Device and equipment inventories will vary per site: refer to established procedures specific to each site.

3.3 A Standard decontamination procedure typically includes but is **not** limited to, the following steps:

a) Receive contaminated container and contents.
b) Remove basket(s) and contents and sort for further reprocessing
c) Disassemble components and remove and dispose of single-use components.
d) Place container lid, filter retaining plate(s) and container base into the washer disinfector so water drains out, or manually wash each component with neutral pH detergent, followed by thorough rinsing and drying.

Note: A detergent with highly acidic or highly alkaline pH could permanently damage the finish of the container. Do **not** use abrasive or metal brushes on containers or container components. Improper cleaning can permanently damage the container finish. Do **not** process in a sonic washer.

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4. Assembly

4.1 Always follow the validated MIFUs for assembly of all containers.

4.2 Container inventories will vary per site; refer to established procedures specific to each site.

4.3 Standard assembly procedures typically include but are not limited to, the following steps:

a) Receive container base, lid, and filter retaining plate(s) from washer disinfector or pass through window

b) Carefully inspect components:

(i) For cleanliness,

(ii) Ensure the gasket is free of any damage including cracks, tears, cuts or shredding.

(iii) Ensure the gasket is properly seated in it retaining groove.

(iv) Check upper edges of the container base and lid for burrs, dents or any damage that may affect the seal or effective use of the container system.

4.4 Place the lid onto the container base making sure it is properly seated.

4.5 Close the latching mechanisms to ensure proper closure.

4.6 Check the retaining plate(s) for proper alignment and fit.

4.7 Check the latching mechanisms and handles for any damage.

4.8 Check instrument basket(s) for missing or loose components; replace or tighten as required.

4.9 Remove any damaged components from service and send for repair according to the MIFU and site based procedures.

4.10 Inspect instruments and assemble into basket(s) as per site based procedure.

4.11 Instrument sets shall be sterilized with all instruments opened, unlocked and disassembled to allow sterilant contact with all surfaces.

4.12 Instrument sets shall be prepared so that the mass is evenly distributed in a single layer within the container unless the container is designed to have more than one layer.

4.13 For employee safety, the combined weight of the wrapped instruments and their container shall not exceed 10 kg (22 lbs).

4.14 Place instrument basket(s) into matching labelled container base.

4.15 Place chemical integrators into set as per site based procedure.

4.16 Assemble filter(s) into retaining plate(s) and firmly seat into position.

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4.17 Label and insert data card. Maintenance of the sterilization container may be documented by initialling the container, usually the data card, during assembly.

4.18 Attach lid to container base

4.19 Close latching mechanisms.

4.20 Secure tamper-evident locking devices.

Note: Do **not** overload instrument basket(s); ensure instruments do **not** touch the lid of the container.

- A rigid sterilization container system shall have a tamper-evident device and a latching mechanism that clearly indicates if the container has been opened after it was sealed and sterilized.
- Do **not** affix any tape or adhesive-backed labels to the container.

4.21 Sterilize containers according to MIFUs and established procedure(s) specific to each site.

5. Sterilizer loading, cooling and unloading

5.1 Always follow the validated MIFUs for containers.

5.2 Standard sterilizer loading procedures typically include but are not limited to, the following steps:

a) Place containers flat on sterilizer shelves.
b) May be sterilized in dedicated loads or in mixed loads with wrapped and peel pouched items.
c) If sterilizing in a mixed load, place container below absorbent wrapped items.
d) Large or heavier container sets should be placed on the middle racks of the cart.
e) Stack containers according to MIFUs and established site-based procedures.

Note: Make sure sterilant access holes on the containers are **not** obstructed.

5.3 Standard sterilizer cooling and unloading procedures typically include but are not limited to, the following steps:

a) Allow containers to cool down to room temperature before handling and transport to sterile storage; proper cool down is necessary to prevent condensation and possible contamination.
b) Transport sterilized containers to appropriate location in sterile storage using ergonomic best practice.

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Note: Eliminate drastic temperature differences by keeping the containers away from ventilation ducts.

6. Storage

6.1 Rigid sterilization containers shall be stored and stacked according to MIFU and standards for sterile storage.

DEFINITIONS

None

REFERENCES

- Non-Alberta Health Services documents
  - *Canadian Medical Device Reprocessing. (Canadian Standards Association)* (CAN/CSA Z314-18)

VERSION HISTORY

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October 2017	Initial approval
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