AHS Provincial Medical Device Reprocessing Working Group

Standard Operating Procedure

Immediate Use Steam Sterilization Containers

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OBJECTIVES

- Identify the general requirements of Immediate Use Steam Sterilization (IUSS) container systems.
- Identify basic structure and anatomy of IUSS container system.
- Identify the decontamination, assembly and inspection process for IUSS container systems.

Note: This SOP only applies to the *container systems used for IUSS*, not the IUSS process itself (see Definitions).

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. Immediate Use of Steam Sterilization containers (IUSS)
 - 1.1 IUSS containers must be used according to the validated manufacturer's instructions for use (MIFU).
 - 1.2 IUSS container systems must be appropriate to accommodate the device intended, sterilization equipment and method of sterilization, and preferably be closed system.
 - 1.3 IUSS container systems shall:
 - a) provide an adequate barrier against viable microbes;
 - b) allow for adequate air removal, sterilant penetration, and evacuation;
 - c) allow direct contact with all surfaces of the medical device;
 - d) be stable under sterilization conditions;
 - e) facilitate ease of presentation to the sterile field;
 - f) protect sterile items(s) during transport; and support aseptic technique for removal of sterilized item.
 - 1.4 IUSS container systems should be opened, used immediately and not stored for later use or held from one case to another.

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- 2. Basic Anatomy and Structure
 - 2.1 IUSS container systems typically include but are NOT limited to the following:
 - a) box-like base;
 - b) removable upper lid with gasket;
 - c) latching mechanism;
 - d) valve perforated top plate;
 - e) silicone valve gasket;
 - f) vent button
 - g) instrument basket typically made of stainless steel with a perforated or mesh bottom.
- 3. Decontamination, assembly, inspection & routine maintenance
 - 3.1 IUSS container systems must be cleaned according to the MIFU. Cleaning can be by either manual or mechanical methods with neutral pH detergent, followed by thorough rinsing and drying.
 - 3.2 Disassembly is required prior to cleaning.
 - 3.3 Any valves should be released and cleaned according to the MIFU.
 - 3.4 Interior baskets should be removed and cleaned after each use.
 - 3.5 Containers are NOT to be stacked on top of another container or another IUSS container.
- 3.6 IUSS container systems shall be inspected prior to use for the following:
 - a) cleanliness:
 - b) catches:
 - c) all nuts;
 - d) bolts;
 - e) screws;
 - f) rivets;
 - g) valve seal;
 - h) noticeable cracking;
 - i) corrosion or pitting;
 - i) misalignment in which the top and bottom do adequately mate.
 - 3.7 IUSS container system must be removed from service due to damage or need for replacement parts.
 - 3.8 Follow container system MIFU and site policies for damaged and repaired devices.

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DEFINITIONS

None



REFERENCES

- Non-Alberta Health Services documents
 - Canadian Medical Device Reprocessing. (Canadian Standards Association) (CAN/CSA Z314-18)
 - o Immediate Use Steam Sterilization Position Statement. (AAMI) (2011).
 - Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities. AAMI (2010). (American National Standard ANSI/AAMI ST79) and (A1: 2010 Arlington, VA: AAMI.)

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