# Packaging of Reusable Critical Medical Devices for Sterilization

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## OBJECTIVES

Devices shall be prepared for sterilization in such a way that the sterilant can move through the device and contact all surfaces.

## APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staff, 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.** Packaging for sterilization shall take into account the following practices:
- 1.1 Packaging shall be appropriate to the sterilization method;
- 1.2 Wrap securely but not too tightly;
- 1.3 Do **not** use staples, pins, or elastics to secure a package;
- 1.4 Arranging contents for order of use (OR instrumentation);
- 1.5 Do **not** mix stainless steel items and linen in the same package;
- 1.6 Separate touching/nesting surfaces of metal or glass with porous material such as a huck towel;
- 1.7 Chemical indicators shall be placed in all packaged devices.
- 1.8 Use standard wrapping techniques. This should include sealing and labelling practices.

**2.** Medical devices to be sterilized shall be placed in:
- 2.1 sterilization pouches in accordance with the manufacturer's instructions or;
- 2.2 a rigid sterilization container or container system that meets the requirements of (CAN/CSA-Z314.14).

**3.** Additional packaging requirements as specified in the manufacturer's instructions and facility procedures shall be followed (e.g., foam corner protectors, tip protectors, silicone matting).

**Note:** Packaging is a critical component of the sterilization process. Improper packaging materials and methods can inhibit steam penetration or lead to failure in maintaining sterility.

**4.** A wrapped or packaged item shall not be placed inside another package unless;
- 4.1 This configuration is supported by the device manufacturer (e.g., an additional protective container or;

4.2 The internal packaging has been validated by the packaging material manufacturer or;

4.3 The health care facility cannot determine if combined packaging should be used. Always follow Manufacturer's Instructions.

**5.** When evaluating a given packaging material or system (e.g., textiles, paper pouches, wrappers and rigid sterilization containers) the health care facility shall;

5.1 Consult with the manufacturer of the material or system and confirm that it is appropriate for the device being sterilized.

5.2 Request and review a copy of the manufacturer's documented evidence that the material or system has been validated to the sterilization cycles used in the health care facility.

**6.** The materials or systems used for packaging shall:

6.1 Allow for adequate air removal, steam penetration, and evacuation;

6.2 Be a barrier to micro-organisms, dust, and vermin;

6.3 Be stable under sterilization conditions;

6.4 Be strong enough to withstand normal handling; and

6.5 Allow for aseptic removal of the sterilized medical device(s).

**Note**: See manufacturer's instructions for the barrier properties and recommended use of single-use textiles and other wrapping materials.

**7.** Release of packages

7.1 If a package is released based on monitored physical parameters and internal chemical indicator results, the internal chemical indicator shall be a Type 5 or Type 6.

## 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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