The aim of this document is to support patient safety related to cleaning and reprocessing of medical devices considered for purchase.

**Purchasing Medical Devices – Patient Safety: Risk Category**

1. Determine the medical device risk category for reusable medical devices using Spaulding’s Classification.

1.1 Non-critical medical devices touch intact skin or clothing and are the lowest risk of transmitting infection.
   
   1.1.1 Routine IPC review is not required; however, IPC may be consulted for specific devices such as those difficult to clean and potentially contacting non-intact skin, e.g., virtual reality devices, or those with components such as fans, vents, filters or water reservoirs, e.g., rapid infuser devices.

   1.1.2 The end-user of the device:
   - Reviews the manufacturer’s instructions for use for recommended products for cleaning and disinfection.
     - May consult a Linen and Environmental Services supervisor or manager to determine if the device can be cleaned and disinfected with available resources and following current protocols.
   - If the manufacturer’s instructions recommend use of products not provided by AHS, e.g., dishwashing soap, or non-supplied disinfectant:
     - Notifies both the vendor and the manufacturer that AHS provided products will be used;
     - Determines next steps/process in collaboration with the manufacturer if warranty/liability issues arises, e.g., if the product breaks down and requires replacing as it can’t be cleaned.

1.2 Critical medical devices enter sterile tissue, and semi-critical medical devices touch mucous membranes or non-intact skin and pose the highest patient risk of infection if they are not handled, cleaned and high-level disinfected or sterilized according to manufacturer’s instructions for use and Alberta Health requirements¹.

   1.2.1 The end-user of the device:
   - Confirms the device can be cleaned, high-level disinfected or sterilized with existing resources, protocols and AHS provided products.
   - Considers stakeholders based on factors such as device complexity, intended use, reprocessing area; technical, maintenance and infrastructure requirements; safety; and state of technology e.g. new, emerging or in use and well-accepted.

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¹ Alberta Health. 2012. Standards for Cleaning, Disinfection and Sterilization of Reusable Medical Devices for Health Care Facilities and Settings
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- Does not purchase semi-critical and critical devices, if:
  - Clear, validated, reprocessing instructions cannot be obtained for the device;
  - The reusable devices cannot be reprocessed in the facility according to the manufacturer's instructions.
- Refers to the AHS Single-Use Medical Device policy if there are no manufacturer’s validated written reprocessing instructions for the device.
- Considers use of a single-use alternative for devices known to be difficult to clean. For example:
  - Long, narrow (< 1 mm diameter) lumens and channels;
  - Valves that cannot be disassembled;
  - Crevices, joints, or surface pores;
  - Instruments that cannot be opened or disassembled for cleaning. Choose a Model that can be disassembled, if one is available;
  - Hinges or ribbing in instruments e.g. forceps, clamps;
  - Rough, irregular, discontinuous surfaces that can entrap or retain soil;
  - Porous materials. Choose smooth surfaces, where possible; and,
  - Luer locks.

Definitions

**Critical medical device**: a medical device that enters sterile tissues, including the vascular system.

**Manufacturer's instructions for use**: means the validated, written directions provided by the manufacturer or distributor of a medical device or product that contain the necessary information for the safe and effective use of the medical device or product.

**End-user** means requester, purchaser, or decision-maker authorizing the purchase.

**Medical device**: means any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

1. Diagnosis, prevention, monitoring, treatment, or alleviation of disease;
2. Diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or handicap;
3. Investigation, replacement, or modification of the anatomy or of a physiological process; or
4. Control of conception; and that does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but that can be assisted in its function by such means.

**Non-critical medical device**: means a medical device which either touches only intact skin but not mucous membranes or does not directly touch the patient.

**Reprocessing**: means the steps performed to prepare a used medical device for reuse.

**Reusable medical device**: means a device designed by the manufacturer, through the selection of materials and/or components, to be re-used.

**Semi-critical medical device**: means a medical device that comes into contact with mucous membranes or non-intact skin, but ordinarily does not penetrate them.

**Single-use**: means a device designated by the manufacturer for single-use only.

**Validated**: means a documented procedure for obtaining, recording, and interpreting the results required to establish that a process for cleaning, disinfection or sterilization of a medical device will consistently yield safe products complying with the CSA Standard Z17664.