Purchasing Medical Devices – Spaulding Risk Classification for End-Users

Note: This best practice recommendation was developed by the Infection Prevention and Control Equipment Purchasing Working Group in consultation with Workplace Health and Safety (WHS), Contracting, Procurement and Supply Management (CPSM), Capital Management and Medical Device Reprocessing Department (MDRD) representatives to help Infection Control Professionals understand the complexity of purchasing medical devices. This recommendation is one of four in a suite of documents to support the pre-purchase approval process of medical devices: Purchasing Medical Devices – Spaulding Risk Classification for End-Users; Purchasing Medical Devices – Forms and Documentation; Purchasing Medical Devices – Pre-purchase Criteria for End-Users; and Purchasing Medical Devices – Roles and Responsibilities.

Terms are defined in the **Definitions** section.

If you have any questions or comments contact IPC at ipcsurvstdadmin@ahs.ca.

The aim of this document is to support patient safety by outlining key elements of the purchase process: forms and documentation for critical and semi-critical medical devices and reprocessing equipment.

Best practice recommendations

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

   1.1 **Non-critical medical devices** contact intact skin or clothing and have 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 or approved for use by AHS, e.g., dishwashing soap or non-supplied disinfectant:
     - Contact the vendor about use of AHS provided products and confirm/verify compatibility in writing, e.g., email.
     - If the products are not compatible or verification isn't provided, determine next steps/process in collaboration with the manufacturer if warranty/liability issues arise, e.g., if the product breaks down and requires replacing as it can't be cleaned.

   1.2 **Semi-critical** and **critical** medical devices

   1.2.1 Semi-critical medical devices contact mucous membranes or non-intact skin and may be reprocessed in areas other than medical device reprocessing departments, e.g., endoscopy.

   1.2.2 Critical medical devices enter sterile tissue and require sterilization according to manufacturer's instructions for use and Alberta Health requirements.[1]
   The end-user of the device:

[1]Alberta Health. 2019. Reusable & single-use medical devices standards: standards for the reprocessing of reusable medical devices and for the use of single-use medical devices in all health care facilities and settings

For more information contact
ipcsurvstdadmin@ahs.ca

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- Contacts the medical device reprocessing department to confirm the device can be cleaned, high-level disinfected or sterilized with existing resources, protocols and AHS provided products.
- Consults stakeholders based on factors such as:
  - Device complexity;
  - Intended use;
  - Medical device **reprocessing** department (MDRD), e.g., confirms device can be reprocessed according to manufacturer's instructions and can be reprocessed in a medical device reprocessing department or other qualified department, e.g., endoscope reprocessing department;
  - Technical, maintenance and infrastructure requirements;
  - Patient and user safety;
  - State of technology e.g., new, emerging or in use and well-accepted.
- 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.
    Note: disposable sheaths or covers do not negate the need for cleaning and disinfection or sterilization of the device as determined by the Spaulding Classification.
- 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.

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Definitions

Critical medical device means 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:

- Diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- Diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or handicap;
- Investigation, replacement, or modification of the anatomy or of a physiological process; or
- 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 that contacts intact skin but not mucous membranes; or does not directly contact 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 once it has been cleaned and reprocessed.
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.

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