OBJECTIVES

- To standardize and provide direction on the use of critical single-use medical devices or semi-critical single-use medical devices in Alberta Health Services (AHS) settings to prevent the transmission of microorganisms and injury to patients.

PRINCIPLES

AHS is committed to patient safety and supports staff knowledge regarding the appropriate use of single-use medical devices and in accordance with the Reusable & Single-Use Medical Devices Standards (Alberta).

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).

ELEMENTS

1. Knowledge

1.1 Users of a medical device shall know if the device is a single-use medical device as outlined within this Policy or if the device can be reused.

1.2 Users of a medical device shall know the risk class assigned to the device (critical, semi-critical or non-critical).
2. Use of Critical or Semi-Critical Single-Use Medical Devices

2.1 A critical medical device or semi-critical medical device shall be treated as a single-use medical device in the event that:

a) the manufacturer has identified the device using labels that include, but are not limited to, the following:

   (i) disposable;

   (ii) consumable;

   (iii) not for reuse or do not reuse;

   (iv) discard after single use;

   (v) do not use twice; or

   (vi) a symbol such as \[2\]

b) the labelling of the device is unclear; or

c) there are no manufacturer’s validated written reprocessing instructions for the device.

2.2 A single patient-use medical device may be used on the same patient in accordance with the manufacturer’s instructions, but shall not be reused on another patient.

a) Where the manufacturer does not provide instructions for duration of use or reuse or some form of reprocessing between each use, users shall follow AHS operational policies.

b) If the manufacturer’s labelling is ambiguous, i.e., labelled single patient-use and also has the single-use symbol, it should be considered a single-use medical device.

   (i) A Medical Device Incident or Problem (MDIP) report must be submitted via the AHS Medical Device Incident or Problem Report form portal with a photo of the labelling.

2.3 Critical or semi-critical single-use medical devices shall only be used on an individual patient for a single procedure and then shall be discarded as per the AHS Waste Management Policy, AHS Biomedical Waste Procedure, AHS Hazardous Chemical Waste Procedure and any applicable processes.

2.4 Critical or semi-critical single-use medical devices shall not be used beyond the expiry date specified by the manufacturer.
2.5 Prior to using a critical or semi-critical single-use medical device that was purchased in a non-sterile state, the device shall be inspected and processed according to the manufacturer’s validated and written instructions, (e.g., dental burrs and orthopaedic plates and screws), and as per applicable AHS policies and processes.

2.6 AHS may purchase single-use medical devices that are reprocessed and redistributed by a commercial reprocessor in accordance with Health Canada requirements and the Reusable & Single-Use Medical Devices Standards (Alberta) i.e., meets the same requirements as a manufacturer of new devices.

2.7 Sterile critical or semi-critical single-use medical devices shall be maintained as sterile until point of use.

2.8 Opened but unused critical single-use medical devices shall be discarded, unless the manufacturer provides validated and written instructions for reprocessing (e.g., orthopaedic plates and screws).

2.9 Single-use medical devices shall be discarded after use (as per Section 2.3 above) unless there was a device-related incident or problem in which case they shall be reported and retained for investigation as per the AHS Medical Device Safety Policy Suite.

2.10 Single-use medical devices shall not be returned to the patient.

3. Monitoring and Reporting

3.1 To support continuous learning, it is essential to report patient safety concerns related to the use of a critical or semi-critical single-use medical device through the AHS Reporting and Learning System for Patient Safety (RLS), (e.g., patient exposure to blood and body fluids related to reuse of critical or semi-critical single-use medical devices). Refer to the AHS Occupational Exposure to Blood and Body Fluids Policy.

3.2 AHS requires all medical device incidents (MDIs) or medical device problems (MDPs) experienced at the point of use to be reported to the AHS Medical Device Safety (MDS) teams via the AHS Medical Device Incident or Problem Report form portal.

3.3 The Infection Prevention and Control Executive and the Senior Medical Officer of Health shall review all reports received on the use of critical or semi-critical single-use medical devices that are not in accordance with this Policy.

   a) Reports on the use of critical or semi-critical single-use medical devices received in accordance with Section 3 of this Policy shall be evaluated to determine if changes can be made to make patient care safer. Such reports may include:

      (i) summary reports from the AHS RLS;
(ii) internal review processes such as medical device reprocessing reviews conducted within AHS health care facilities; and

(iii) external review processes such as those conducted by Accreditation Canada and Alberta Health that include standards pertaining to single-use medical devices.

4. Exceptions

4.1 For direction on the exceptions process, see Appendix A: Single-Use Medical Device Exception Process. Based on this exception process, single-use medical devices may be considered for reuse:

a) after reprocessing by a commercial reprocessor, in accordance with applicable AHS policies and Health Canada’s requirements for reprocessing and distribution of medical devices originally authorized and labelled as single-use medical devices.

b) When requests have been approved, refer to the direction in Sections 4.3 and 4.4 of this Policy.

4.2 Requests for exceptions for reuse shall be based on:

a) patient safety and clinical effectiveness of the device to perform as originally intended by the manufacturer;

b) Infection Prevention and Control standards, policies and processes; and

c) medical device reprocessing capacities and capabilities.

4.3 Evaluation of exception requests shall be:

a) evaluated using a multi-level approach. The decision to deny the request may occur at any level. The levels are:

   (i) Provincial Infection Prevention and Control Committee;

   (ii) Infection Prevention and Control Executive and Senior Medical Officer of Health; and

   (iii) AHS committees reporting to the Executive Leadership Team.

4.4 Refer to Infection Prevention and Control’s Single-Use Medical Devices external website for existing exceptions.

5. Exceptions for Retention

5.1 Critical or semi-critical single-use medical devices may be retained for investigation as per the AHS Medical Device Safety Policy Suite. These devices are not reused.
DEFINITIONS

Commercial reprocessor means a company that reprocesses medical devices and offers its activities and products as a service in compliance with the Food and Drugs Act (Canada) and the Medical Devices Regulations (Canada) and the corresponding requirements to meet standards for safety, effectiveness and labelling.

Critical medical device means a medical device that enters sterile tissues/vascular system, or enters normally sterile cavities and therefore presents a high risk of infection if the medical device is contaminated with any organisms, including bacterial spores. Examples include but are not limited to the following: needles (including acupuncture needles), lancets, syringes, suture removal kits, urinary catheters, biopsy forceps, infusion supplies and devices, such as catheters, lines (e.g., intravenous administration tubing) and access ports.

Infection Prevention and Control Executive means, for the purposes of this Policy, a member of Alberta Health Services as defined in the Alberta Health (2011) Standards for Infection Prevention and Control - Accountability and Reporting.

Manufacturer means a person (including a partnership, firm or association) who sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and with respect to the medical device, is responsible for the following: designing, manufacturing, assembling, processing, labelling, packaging, refurbishing, modifying, or assigning the medical device an intended purpose, whether those tasks are performed by that person or on their behalf.

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 a human being for any of the following purposes:

- 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 physiologic process;
- control of conception, and that does not achieve its principal intended purpose in or on the human body by pharmacological, immunological, or metabolic means, but that can be assisted in its function by such means.

Medical device incident (MDI) means, according to Health Canada, a medical device problem that has led to the death or a serious deterioration in the state of health of a patient, medical device user, or other person, or could do so were it to recur; serious deterioration in health means a life-threatening disease, disorder or abnormal physical state, the permanent impairment of a body function or permanent damage to a body structure, or a condition that necessitates an unexpected medical or surgical intervention to prevent such a disease, disorder or abnormal physical state or permanent impairment or damage. MDIs include any that occur as a result of an off-label/abnormal use. This is the equivalent of a Serious Clinical Adverse Event (CAE) or Near-Miss Serious CAE, or a worker incident with serious harm, at AHS.

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. Examples include
limited to the following: electrocardiogram (ECG) electrode patches and disposable non-sterile procedure gloves.

**Opened but unused critical single-use medical device** means a disposable single-use medical device whose sterility has been breached or compromised, or whose sterile package was opened but the medical device has not been used on a patient, and has not come into contact with blood, tissue or body fluids.

**Patient** means all persons, inclusive of residents and clients, who receive or have requested health care or services from Alberta Health Services and its health care providers. Patient also means, where applicable:

a) a co-decision-maker with the person; or  
b) an alternate decision-maker on behalf of the person.

**Point of use** means, for the purposes of this Policy, a specific point in time and place at which a medical device is used on a patient.

**Reprocessing** means the cleaning, disinfection and/or sterilization of a potentially contaminated medical device so that it is safe and effective for use on the patient.

**Risk class** means, for the purposes of this Policy, the classification based on the risk of infection involved with the use of the medical device on a patient. The three risk classes are:

- critical medical devices  
- semi-critical medical devices; and  
- non-critical medical devices.

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

**Single patient-use medical device** means a semi-critical medical device that is labelled by its manufacturer for use on a single patient as described in the manufacturer's instructions, and not for reuse on another patient. The manufacturer instructions may:

- Allow an extended episode of use on a single patient;  
- Allow re-use on a single patient;  
- Where the medical device is reusable and its reusability is limited, the label should indicate the maximum number of allowable reuses; and  
- The manufacturer's instructions may describe some form of reprocessing between each use on the same patient.
The manufacturer may use terms, including but not limited to the following, to designate a device for single patient use:

- Single patient use
- Single patient multiple use
- A symbol such as

Single-use medical device means a critical or semi-critical medical device labelled by their manufacturer to be used only once. The manufacturer may use terms, including but not limited to the following, to designate a device for single-use only:

- disposable;
- consumable;
- not for re-use or do not re-use;
- discard after single use;
- do not use twice; or
- a symbol such as

Validated means a confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

1. The objective evidence needed for validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.
2. The term “validated” is used to designate the corresponding status.
3. The use conditions for validation can be real or simulated.

Validated written reprocessing instructions means the validated, written directions provided by the manufacturer or distributor of a medical device or product, that contain the necessary information for cleaning, disinfection, and/or sterilization of a potentially contaminated medical device so that it is safe and effective for use on a client.

Note: The term may also be used to refer to written instructions for use developed internally or by a commercial reprocessor that have been validated by an approved laboratory.

REFERENCES

- Appendix A: Single-Use Medical Device Exception Process
• Alberta Health Services Governance Documents:
  o Biomedical Waste Procedure (#ESM-01-01)
  o Hazardous Chemical Waste Procedure (#ESM-01-02)
  o Medical Device Incident or Problem Reporting Procedure (#PS-103-03)
  o Medical Device Safety Policy Suite (#PS-103)
  o Occupational Exposure to Blood and Body Fluids Policy (#1111)
  o Waste Management Policy (#ESM-01)

• Alberta Health Services Resources:
  o Blood and Body Fluid Exposure (BBFE) (Workplace Health & Safety)
  o Critical and Semi-Critical Single-Use Medical Devices Policy Frequently Asked Questions
  o Medical Device Incident or Problem Report Electronic Form
  o Single-Use Medical Device List of Approved Exceptions

• Non-Alberta Health Services Documents:
  o CAN/CSA Z314-18 Canadian medical device reprocessing
  o Reusable & Single-Use Medical Devices Standards (Alberta)
  o Standards for Infection Prevention and Control – Accountability and Reporting (Alberta)

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APPENDIX A

Single-Use Medical Device Exception Process

Appendix A

Clinical Stakeholder identifies the need for an exception to AHS Single-Use Medical Devices Policy

Step 1: Examine and Document the Reuse & Reprocessing Considerations

Consult with some or all of the following:
- Clinical experts
- Medical device reprocessing
- Clinical engineering
- Infection Prevention and Control
- Contracting, Procurement & Supply Management
- Patient Safety
- Legal Services

Consider:
- Ability to clean
- Sterility / disinfection status
- Residual disinfection / sterilization products on device
- Material degradation
- Functionality of device
- Ability of device to perform as intended by original manufacturer

Prepare briefing note, include the following:
- current use / reuse practices across AHS and in Canada
- published validation and guidelines
- cost implications, if available

Step 2: Confirm Safety and Clinical Effectiveness Considerations

Agreement to proceed sought from:
- Provincial IPC Committee
- Senior Medical Officer of Health
- AHS IPC Executive

Consider:
Has the safety and clinical effectiveness of the reused / reprocessed single-use medical device been established?

Agreement to proceed?

Step 3: Infection Prevention and Control Confirms Organizational Engagement Consideration

Agreement to proceed to be sought from:
- Clinical Operations Executive Committee
- Quality and Safety Executive Committee
- Executive Leadership Team

Consider:
Are there organization-wide operational or patient safety implications not yet identified?

Agreement to proceed?

Step 4: Infection Prevention and Control Confirms Organizational Approval

CEO Approves?

Step 5: Document and Communicate Decision

AHS stakeholders:
- Notify clinical users, including MDR departments
- Notify contracted agencies / services as applicable
- Bring to Provincial IPC Committee
- Update list of approved exceptions on Clinical Policy webpage

Alberta Health:
- Notify the Alberta Health Chief Medical Officer of Health
- Include in the AHS IPC annual report to Alberta Health

Single-use medical device not eligible for exception. Do not proceed with request.