Critical and Semi-Critical Single-Use Medical Devices Policy FAQ

AHS has revised the Single-Use Medical Device policy in 2021 to align with the 2019 Alberta Health Reusable & Single-Use Medical Devices Standards as part of the regularly scheduled policy revision process. Please contact Policy Services at policy@ahs.ca if you have additional questions about this policy. The Policy Services website is the official source of current approved policies and procedures.
If you have any questions or comments contact IPC at ipcsurvstdadmin@ahs.ca.

Frequently asked questions

Questions	Responses
Section 1: What everyone needs to know about single-use medical devices	
1. Why was a policy for single-use medical devices developed?	• Healthcare professionals understand the proper use of all medical devices including single-use devices. • Reusing medical devices that are manufactured for single-use may put patients at a serious safety risk including patient blood and body fluid exposure. • The policy standardizes and provides direction on the use of critical and semi-critical single-use medical devices in Alberta Health Services (AHS) settings to prevent the transmission of microorganisms and injury to patients.
2. To whom does this policy apply?	• Compliance with the Policy 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).
3. What are single-use devices?	• Alberta Health, 2019 Reusable & single-use medical devices standards define single-use devices as critical and semi-critical medical devices labelled by their manufacturers to be used only once. • Single-use medical device are intended for use on a single patient for a single procedure and then discarded. • Single-use medical devices are designated as such by the manufacturer on the labelling and instructions for use. The manufacturer may use labels and terms such as: ○ disposable; ○ not for re-use or do not re-use; ○ discard after single-use; ○ do not use twice; ○ or a symbol such as. 
4. What are some examples of single-use medical devices?	• A critical medical device is a device that penetrates the skin or mucous membranes or enters normally sterile cavities. • Examples of single-use critical devices include but are not limited to: needles (including acupuncture needles), intravenous catheters, saline locks and administration sets, dialysis blood lines, access ports, lancets, sutures, staples, most implants, single-use suture removal kits, single-use urinary catheters, and single-use biopsy forceps. . • A semi-critical medical device comes into contact with mucous membranes or non-intact skin but ordinarily does not penetrate them. • Examples of semi-critical single-use devices include but are not limited to: sterile bandages and other single-use skin wound management devices; tongue depressors;

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Questions	Responses
	single-use oral swabs; single-use trans-rectal probes, and vaginal, nasal and rectal specula; single-use respiratory oral endotracheal tubes, airway devices, and suction devices. • **Note:** Some critical and semi-critical devices in the same categories as those listed here as single-use, may be manufactured as reusable for a single-patient or reusable for multiple patients with appropriate cleaning, disinfection and sterilization between uses; this would be apparent in the device labeling and instructions for use.
5. Does the Single-Use Medical Devices policy cover non-critical medical devices?	• No, the policy does not cover non-critical devices as it aligns with the Alberta Health, 2019 Reusable & single-use medical devices standards definition of single-use devices: critical and semi-critical medical devices labelled by their manufacturers to be used only once. • A non-critical medical device refers to devices that touch only intact skin but not mucous membranes, or devices that do not directly touch the patient. • Examples of single-use non-critical devices include but are not limited to procedure gloves, disposable gowns, procedure masks, single-use electrocardiogram (ECG) electrode patches and disposable non-sterile procedure gloves.
6. Is there a difference between a single-use device and a single patient-use device?	• Yes. A single patient-use or single-patient-reuse only medical device is a semi-critical medical device that is intended by the manufacturer for reuse or extended use on a single patient only as described in the manufacturer's instructions for use. • Single-patient reuse only devices are designated by the manufacturer for single-patient-reuse only in the labelling and the instructions for use: ○ Single patient-use ○ Single patient multiple use ○ A symbol such as  • Examples of single patient-use medical devices include but are not limited to single patient use oxygen tubing, cannula and masks, nebulizers, metered dose inhaler spacers, and infant oxygen sensors. • **Note**: Similar devices used for the same or similar purposes may be designated as single-use, single-patient-reuse-only, or reusable between patients, depending on the manufacturer's reprocessing validation, testing and intended use. Always follow the manufacturer's instructions for use unless there is a documented AHS exception, or in the case of ambiguous labelling, i.e., device labelled single patient-use and also has the single use symbol it is considered a single use medical device.
Section 2: What is new/different in the updated Single-Use Medical Device Policy	
1. What has changed in the updated Single-Use Medical Device policy?	• The AHS Critical and Semi-Critical Single Use Medical Device Policy was updated to align with the 2019 Alberta Health 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 healthcare facilities and settings. Changes include: ○ Expiry dates, commercial reprocessing, and patient requests for return of single-use devices (devices are not be returned to patients); ○ Single-patient re-use devices usage and definition, including actions to take if device labelling is ambiguous, e.g., intended for single patient-use but single-use label or symbol;

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	○ Updated process for reporting of medical device incidents or problems (MDIP) including ambiguous labelling. ○ Updated definitions, e.g., validated written reprocessing instructions, commercial reprocessor and single-patient re-use devices including international symbol.
2. Are exceptions still allowed in the updated policy?	• Yes. As per previous direction in the Standard for Reusable and Single-Use Medical Devices (Alberta), exceptions may be allowed to the single-use medical devices standard in accordance with Ministerial Directive D4-2019, when they are based on best practices in the respective healthcare field.
3. What is ambiguous labelling? What is adequate labelling? What action is required if ambiguous labelling or inadequate is identified?	• Ambiguous labelling, in this context, means the manufacturer's intended reusability (single-use, single-patient-reuse only, reusable between patients) is unclear to the user, e.g., the device may be labelled "single patient-use" but has the single use symbol. If device reusability labelling is ambiguous the user should: ○ Consider the device a single use medical device and ○ Report the problem and request clarification via the Medical Device Incident or Problem (MDIP) reporting process (see below). • Inadequate labelling in this context applies to reusable medical devices, and means the manufacturer did not define reusability parameters, e.g., number of uses, length of time of use before reprocessing and/or disposal; and/or did not provided appropriate instructions for reprocessing between uses (for reusable single-patient-reuse or reusable between patients devices). If labelling is inadequate, the user should: ○ Follow organization operational policies while awaiting clarification, e.g., AHS processes for cleaning nasal cannula or metered dose inhaler. ○ Report and request clarification via the MDIP reporting process. • Medical Device Incident or Problem (MDIP) Reporting: ○ Complete and submit a Medical Device Incident or Problem (MDIP) report via the AHS Medical Device Incident or Problem Report form portal: https://share.albertahealthservices.ca/teams/CPSM/ClinicalSupportEngagement/AHSMDIPReporting/SitePages/Home.aspx ○ Describe the problem and include photos of the unclear labeling wherever possible.
4. Allowance of Commercial Reprocessors of single-use medical devices in some circumstances.	• A commercial reprocessor is a company that reprocesses medical devices and offers its activities and products as a service in compliance with the Food and Drugs Act and the Medical Devices Regulations and the corresponding requirements to meet standards for safety, effectiveness, (e.g., reprocessing parameters and limitations such as the number of times the device can be reprocessed); and labelling.
5. When may AHS use commercial reprocessors?	• AHS may use devices supplied by commercial reprocessors: 1) AHS may purchase single-use medical devices reprocessed and redistributed by a commercial reprocessor. 2) In accordance with the Single-Use Medical Device policy exception process a single-use medical device may be considered for reuse: ○ 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.

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	• When requests have been approved, refer to the direction in Section 4.3 and 4.4 of this Policy.
Section 3: Single-Use Medical Devices Policy Implementation Questions	
1. Are there documents or educational tools to support the single-use medical device policy?	• Yes. The following resources are available on AHS IPC External Website, Single-use Medical Device page: ○ Poster ○ New Needle, New Syringe Info Sheet ○ New Needle, New Syringe Video ○ Safe Injection Video
2. Do I have to report patient safety concerns related to single-use medical devices?	• Yes. It is essential to report patient safety and other concerns related to any medical device, including single-use devices, to support continuous learning and device and safety improvements. • AHS policy requires all Medical Device Incidents (MDI) or Medical Device problems (MDP) experienced at the point of use to be reported to AHS Medical Device Safety (MDS). MDS in turn reports to vendors and Health Canada on your behalf, facilitates device and labelling investigations and improvements, and tracks and trends reports province-wide for early warning signals of larger scope issues. • Reports may be submitted via the AHS Medical Device Incident or Problem (MDIP) Report form via the AHS Medical Device Incident or Problem Report form portal: https://share.albertahealthservices.ca/teams/CPSM/ClinicalSupportEngagement/AHSMDIPReporting/SitePages/Home.aspx. and/or the AHS Reporting and Learning System (RLS) using the RLS-MDIP form. • Medical Device Incident 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. • Medical Device Problem means, according to Health Canada, an actual or potential deficiency that may affect product performance or safety, a defect, malfunction or fault, a failure of the medical device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions for use (MIFU), or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use. This includes any medical device, labelling, or packaging quality issue or safety hazard, whether or not the medical device affected a patient or other person. • Reports about single-use medical devices received in accordance with Section 3 of the Policy will be evaluated to determine if changes can be made to make patient care safer. • Refer to the Medical Device Safety Policy suite for additional information. ○ Policy: Medical Device Safety

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	○ Procedure: Medical Device Incident or Problem Reporting ○ Procedure: Medical Device Safety - Preparing & Shipping for Investigation
3. Regarding clause 2.5 in the policy requiring opened but unused critical single-use medical devices to be discarded, unless the manufacturer provides validated and written instructions for reprocessing (e.g., orthopaedic plates and screws)". What if the manufacturer's instructions are not clear or do not include a cleaning step?	• Some sterile packaged single-use devices may be reprocessed if the package was opened but not used, typically orthopedic implants, if that is included in the manufacturer's instructions for use. • Not all similar sterile single-use devices have the same validations and instructions, as to whether or not they can be reprocessed if opened but unused. • If manufacturer's instructions are not clear or if reprocessing instructions do not include a cleaning step (reprocessing by definition includes a cleaning step), discard the device and report the issue via the AHS Medical Device Incident or Problem Report form portal: Home > Teams > CPSM> Medical Device Safety > Medical Device Incident or Problem Reporting.
4. Can critical or semi-critical single-use devices be returned to the patient at their request?	• No. The policy, section 2.10 includes direction for the critical single-use medical devices to be discarded after use and not returned to the patient (e.g., breast implants, pacemakers)." • If the patients is requesting devices, e.g., implants they purchased themselves to be returned to them so they can investigate the implanted device for potential adverse effects, e.g., implants they purchased themselves, such as breast implants, it may be helpful to inform them that: ○ Medical devices, including single-use medical devices are to be retained by AHS for investigation as per the AHS Medical Device Safety Policy Suite. ○ There is an expectation the Medical Device Safety Policy & Procedures be followed for reporting and device investigation for any suspect device at AHS, e.g., ruptured breast implant, removed at AHS. ○ Returning explanted suspect devices to patients is not part of that policy/procedure. ○ AHS keeps many suspect devices on Legal Hold for 10 years. • If the suspect device was purchased by the patient before implant, there may be grounds to consider returning it to the patient after the reporting and device investigation steps were complete. In that case: ○ A patient request should be forwarded to the Medical Device Safety (MDIP@ahs.ca) who will consult with Legal Services. • Legal Services will determine, on a case-by-case basis, as to whether the implant could be returned to the patient after the AHS reporting and investigation steps were complete.
Section 4: Single-Use Medical Device Exceptions	
1. Are exceptions allowed for the Single-Use Medical Device policy?	• Yes. Exceptions may be allowed to the single-use medical devices standard in accordance with Ministerial Directive D4-2019, when they are based on best practices in the respective healthcare field. • 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: ○ after reprocessing by a commercial reprocessor, in accordance with applicable AHS policies and Health Canada's requirements for reprocessing and

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	distribution of medical devices originally authorized and labelled as single-use medical devices. ○ when requests follow the process in Appendix A and outlined in Section 4.3 and 4.4 of the Policy. • Requests for exceptions are based on: ○ patient safety and clinical effectiveness of the device to perform as originally intended by the manufacturer; ○ Infection Prevention and Control standards, policies and processes; and, ○ Medical device reprocessing capacities and capabilities. • Evaluation of exception requests are evaluated using a multi-level approach. The decision to deny the request may occur at any level. The levels are: ○ Provincial Infection Prevention and Control Committee; ○ Infection Prevention and Control Executive and Senior Medical Officer of Health; and ○ AHS committees reporting to the Executive Leadership Team. • There are currently Four Approved Exceptions in relation to the AHS Critical and Semi-Critical Single-Use Medical Device Policy.

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