Management of Loaned, Reusable Critical and Semi-Critical Medical Devices Frequently asked Questions

AHS revised the Management of Loaned, Reusable Critical and Semi-Critical Medical Devices policy in 2022 to align with the 2019 Alberta Health Reusable & Single-Use Medical Devices Standards and AHS policies and processes, 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.

Refer to the Management of Loaned, Reusable Critical and Semi-Critical Medical Devices Policy

Questions	Responses
Section 1: What everyone needs to know about loaned and trialed medical devices	
1. What is a loaned or trialed medical device?	**Loaned, reusable medical devices** means a critical and semi-critical medical device that is used by a healthcare facility under an arrangement based on lending, lease, consignment or trial use of new medical devices. **Note 1:** Organizations that include more than one healthcare facility and follow common policies and procedures would not be considered to be loaning devices. **Note**: Vendor-owned devices that are remaining within a facility for extended periods (e.g., three months or longer or as otherwise specified in unit procedures) are treated in the same manner as owned devices.
2. What is a critical or semi-critical medical device?	Critical medical device is defined as a medical device that enters sterile tissues/vascular system or enters normally sterile cavities; therefore, presents a high risk of infection if the medical device is contaminated with any organisms, including bacterial spores. A semi-critical medical device(s) is defined as a medical device that comes into contact with mucous membranes or non-intact skin but does not penetrate them.
3. Why was a policy for management of loaned and trialed medical devices developed?	The provincial AHS Management of Loaned, Reusable Critical and Semi-Critical Medical Devices Policy Management of Loaned, Reusable Critical and Semi-Critical Medical Devices was created in 2017 (and updated in 2022) to standardize the process, timelines, and requirements for management of all loaned, reusable critical and semi-critical medical devices intended for use on a patient.
4. Does this policy apply to all AHS staff?	Yes, this policy applies to all Alberta Health Services employees, members of the medical staff, midwifery staff, students, volunteers, and other persons acting on behalf of or in conjunction with Alberta Health Services (including contracted service providers as necessary.
5. Are there circumstances where the policy does not apply?	Yes, internal transfers of non-vendor items follow provincial or site-specific, approved internal resources or processes (e.g., Standard Operating Procedures) to transfer, log, and track medical devices.
6. Why was the Management of Loaned, Reusable Critical and Semi-Critical Medical Devices policy revised?	The policy required a scheduled review and update. During the review the following minor policy updates were incorporated to reflect current practices, terminology, and provide clarity. Updates were made to:

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	• Align with 2019 Alberta Health standards for reusable and single-use medical devices and CSA standard Canadian medical device reprocessing CAN/CSA Z314-18. • Provide additional definitions and align with current AHS definitions such as accountable leader, close calls, critical medical device, hazard, medical device, performance qualification, semi-critical medical device.
7. What is the standardized process for managing vendor-supplied loaned and trialed medical devices?	All requests for loaned, leased or consigned medical devices are initiated through the manager or designate: • With sufficient time to allow for delivery to the site within required timeframes. • Through a purchase requisition which creates a purchase order number which is required for medical device tracking (to patient). • Reprocessing and sterilization staff or departments receive loaned, leased or consigned medical devices within designated timeframes in advance of use to ensure all required processes can be safely completed.
8. What is considered sufficient time for the reprocessing department to receive loaned, reusable critical and semi-critical medical devices and allow for delivery to the site?	Reprocessing and sterilization staff or departments receive loaned, leased or consigned medical devices within designated timeframes in advance of use to ensure all required processes can be safely completed, such as: • Devices that have been previously reprocessed at the site are received by Medical Device Reprocessing Departments (MDRD) or designate a minimum of two business days (48 hours) before use. • Devices that have never been reprocessed at the site and/or for devices requiring a new cycle not usually used or programmed into the machine, are received by MDRD or designate a minimum of three business days (72 hours) before use. • Devices that are not received by MDRD or designate within the stated times to allow for required inventory, inspection, documentation and reprocessing are not accepted and the operating room is notified. • Devices received outside of the appropriate timeframe are considered a reportable hazard as outlined in Section 2.
9. What is considered a business day?	A business day means any day except any Saturday, any Sunday, or any day which is a legal holiday.
10. Why are the timelines important?	The MDRD or designate verify that the healthcare setting can follow required processes for inventory, inspection, and reprocessing before use of the loaned, leased or consigned device(s), that include but are not limited to: • Confirming and following the manufacturer's instructions for use (MIFU) for reprocessing; • Ensuring sufficient resources are available on site; • Completing performance qualification, if required; and • Completing inspection, disassembly, cleaning, assembly, and sterilization/disinfection, and documentation according to AHS and Alberta Health requirements and CSA standards.
11. Why is three business days (72 hours) the minimum amount of time given for	Three business days (72 hours) was established as the minimum amount of time to receive the device so that MDRD can confirm (as with a new set) the

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the MDRD or designate to receive devices that have never been reprocessed at the site and/or for devices requiring a new cycle not usually used or programmed into the sterilizer?	decontamination process/manufacturer's instructions for use can be followed, e.g., specified enzymatic cleaner, wrappers/containers required, documentation completed and ability to perform the right sterilization cycle. It is preferred to receive the devices that have never been reprocessed at the site earlier, if possible.
12. If all the reprocessing supplies, e.g., brushes are not sent with the sets what actions are necessary to accept the device?	Receiving devices three days (72) hours before use allows the MDRD to confirm that all supplies, e.g., sterilizing and cleaning supplies including brushes and filters that are required to reprocess the devices are made available to the MDRD. If supplies are missing the MDRD contacts the vendor/manufacturer to request reprocessing supplies as required.
13. What information is required from the vendor/manufacturer or site?	The following information is needed in writing, i.e., paper and digital formats, each time the medical device(s) are delivered to the facility, i.e., for each pan, in the specific system: • An accurate and itemized list of instruments or instrument set contents; • Detailed pictures or diagrams of devices, instrument sets, and complex instruments; • The manufacturer's validated instructions for: (i) disassembly (as necessary); (ii) decontamination (cleaning and disinfection); (iii) appropriate packaging; (iv) the method and parameters of sterilization; and (v) any additional special considerations for use and care of the device(s) (e.g., functionality testing); (vi) documentation. The information (set photo, content list) should be accurate, logically organized and easy to follow by any level of staff. Education for staff as needed on the use, cleaning, and the correct reprocessing and sterilization of the medical devices if the manufacturer's instructions require different sterilization parameters or unfamiliar cleaning solutions.
14. What actions are taken after the manufacturer/vendor supplies the above information?	The MDRD confirms manufacturers/vendors: • are in compliance with CSA Standards Management of Loaned, Reusable Canadian Medical Device Reprocessing Medical Devices Z314-18 that state loaner medical devices have not been used on animals or cadavers. • have a system to track the medical devices; • have a Medical Device Active License, Special Access Program or Investigational Testing Authorization number(s) for the loaned, leased or consigned devices; and • have verified the weight of each loaned, leased or consigned item (e.g., instrument tray and the appropriate container), does not exceed 10 kilograms, in accordance with CSA standards.
15. Why is there a weight limit for items?	To support employee safety, the combined weight of the wrapped instruments and their container must not exceed 10 kg (22 lbs).

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16. What is considered an adverse event or close call?	Adverse event means an event that could or does result in unintended injury or complications arising from healthcare management, with outcomes that may range from death or disability to dissatisfaction, or require a change in care such as prolongation of hospital stay, e.g., if reprocessing and sterilization staff or departments do not receive the medical devices following the timelines in the policy, it is considered an adverse event: • Loaned reusable medical devices previously reprocessed at the site received by MDRD or designate a minimum of two business days (48 hours) before use. • Loaned reusable medical devices that have never been reprocessed at the site and/or for devices requiring a new cycle not usually used or programmed into the sterilizer, received by MDRD or designate a minimum of three business days (72 hours) before use. Close call means an incident that has potential for harm and is intercepted or corrected prior to reaching the patient.
17. How are adverse events close calls or hazards reported?	Adverse events, close calls or hazards according to the AHS Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events Policy suite which includes but is not limited to: • The Reporting Learning System for Patient Safety with a copy to the Accountable Leader (e.g., Executive Director Surgery); and • Completion of a Medical Device Incident or Problem (MDIP) report as per the AHS Medical Device Safety Policy Suite.

18. What has changed in the updated policy?	In addition to minor wording changes for clarification:
	• Edits were made to the process for reporting adverse events, close call or hazards to reflect current practice, i.e., notification of the accountable leader (e.g., executive director, surgery);
	• Details were added about completion of a Medical Device Incident or Problem (MDIP) report. If reprocessing and sterilization staff or departments do not receive the medical devices following the timelines in the policy, these are considered an adverse event:
	  ○ Loaned reusable medical devices previously reprocessed at the site received by MDRD or designate a minimum of two business days (48 hours) before use.
	  ○ Loaned reusable medical devices that have never been reprocessed at the site and/or for devices requiring a new cycle not usually used or programmed into the sterilizer, received by MDRD or designate a minimum of three business days (72 hours) before use.

19. Did stakeholder feedback identify any issues that are not addressed in this policy?	Yes. Stakeholders identified the need for a provincial process on internal loaners, e.g., from one AHS facility to another. The provincial MDR working group will develop an internal process.

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