STANDARD	Standards for Single-use Medical Devices	DOMAIN
VI-30.STND.1		Clinical Guidance

Sponsor: Corporate Director, Infection Control	**Date Approved:** June 6, 2023
Policy Lead(s): Infection Control Professional, Infection Prevention	**Date Effective:** September 22, 2023
	Date of Next Review: September 2026

For further information please contact covenantpolicy@covenanthealth.ca

Purpose Statement:

The purpose of this standard is to provide the requirements necessary for the safe and appropriate use of critical single-use **medical devices** or semi-critical **single-use medical devices** in Covenant Health facilities to prevent the transmission of microorganisms and minimize the risk of harm to **patients.**

Parent Policy:

VI-30 Single-Use Medical Devices

Applicability:

This standard is applicable in all Covenant Health facilities and applies to all Covenant Health employees, medical staff, volunteers, students, contractors and any other persons acting on behalf of Covenant Health.

Responsibility:

All Covenant Health employees, medical staff, students, volunteers and any other persons acting on behalf of Covenant Health.

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 

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** instructions between each use, users shall follow relevant Covenant Health operational standards, guidelines, and 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 using the Medical Device Incident or Problem (MDIP) Report Form if manufacturer instructions and labelling are unclear and/or ambiguous.

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 Covenant Health waste management guidelines and operational procedures.

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 Covenant Health policies and processes.

2.6 Covenant Health may purchase single-use medical devices that are reprocessed and redistributed by a **commercial reprocessor** in accordance with Health Canada requirements and the Alberta Health Reusable & Single-Use Medical Devices Standards (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 Alberta Health Services (AHS) Medical Device Safety Policy.

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 Covenant Health 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 Covenant Health Occupational Exposure to Blood and Body Fluids Policy.

3.2 Covenant Health requires all medical device-related harm, near-misses, hazards, and quality problems experienced at point of use to be reported using the Medical Device Incident or Problem (MDIP) Report Form .

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 Covenant Health RLS;

(ii) internal review processes such as medical device reprocessing reviews conducted within Covenant Health 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 Covenant Health 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) Covenant Health committees reporting to the Executive Leadership Team.

4.4 Refer to AHS Infection Prevention and Control's (IPC) 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. 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), according to Health Canada refers to a medical device problem that takes place in a hospital. A **Medical Device Problem (MDP)** is a problem related to inadequate labelling or instructions for use, a failure of the device or a deterioration in its effectiveness, an actual or potential deficiency that may affect product performance or safety, a serious deterioration in the patient's health (possibly related to a medical device or death or the potential to lead to death if the device is used again. As of 2019, hospitals are required to report medical device incidents.

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 but are not 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 Covenant Health 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.

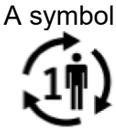
Semi-critical medical device means a medical device that comes into contact with mucous membranes or non-intact skin, but does not penetrate them.

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.

Relevant Covenant Health Policy and Policy Support Documents:	
A.	**Policies:** VI-30 Single-use Medical Devices III-45 Clinical Adverse Events, Close Calls and Hazards
B.	**Procedures:** III-45.PROC.1 Immediate Management of Clinical Adverse Events, Close Calls and Hazards

	III-45.PROC.2 Disclosure of Harm III-45.PROC.3 Ongoing Management of Clinical Adverse Events, Close Calls and Hazards
C.	**Guidelines:**
D.	**Job aids:** Appendix A - Single-Use Medical Device Exception Process
E.	**Standards:**

Keywords:

References:

Covenant Health Resources

- Waste Management Principles and Guidelines
- Blood and Body Fluid Toolkit
- Medical Device Incident or Problem (MDIP) Report Form .
- Medical Device PLEASE Process
- Medical Device Quarantine and Hold Label

Alberta Health Services Resources

- Single-Use Medical Device List of Approved Exceptions
- PS-103 Medical Device Safety Policy

Non-Alberta Health Services Documents:

- CAN/CSA Z314-18 Canadian medical device reprocessing
- Reusable & Single-Use Medical Devices Standards (Alberta Health)
- Standards for Infection Prevention and Control – Accountability and Reporting (Alberta Health)
- About medical device problems - Canada.ca

Past Revisions:

December 7, 2018

September 12, 2014

November 1, 2011

November 1, 2010

Alberta Health Services Policy **PS-07 Critical and Semi-Critical single-Use Medical Device** is adapted for use by Covenant Health

Appendix A

Single-Use Medical Device Exception Process