PPG-00719

Single Use Medical Devices

Area	Infection Prevention and Control
Section	General
Subsection	N/A
Document Type	Policy
Scope	All Health Care Providers

Approved By	**Original Effective Date**	**Revised Effective Date**	**Reviewed Date**
Glenda Short, Director Clinical Programs & Services	2016-May-25	N/A	N/A

DEFINITIONS

Cleaning: The physical removal of foreign (e.g., dust, soil) and organic material (e.g., blood, secretions, excretions, microorganisms). Cleaning physically removes rather than kills microorganisms. It is accomplished with water, cleaning agents (e.g., soap, detergent, cleaner/disinfectant) and manual friction. Cleaning must be performed before high level disinfection or sterilization.

Client: An individual who accesses and/or receives health care related services from a Prairie Mountain Health (PMH) facility or program. Clients may be patients in an acute care setting, residents in a personal care home or clients in a community program or facility.

Critical Medical Device: Medical devices that enter/penetrate the skin or mucous membrane, and/or enter sterile tissues/vascular system through which blood flows and/or enter normally sterile cavities. Such devices present a high risk of infection if the device is contaminated with any organisms, including bacterial spores. Critical medical devices must be reprocessed by meticulous cleaning followed by sterilization. Examples of Critical Medical Devices include but are not limited to surgical instruments, biopsy forceps, foot care equipment, dental hand pieces, needles (including acupuncture needles), lancets, syringes, suture removal kits, urinary catheters, infusion supplies and devices such as catheters, needles, tubing and ports.

Decontamination: The process of cleaning, followed by the inactivation of microorganisms, in order to render an object safe for handling.

Disinfectant: A chemical agent that kills most disease-producing microorganisms, but not necessarily bacterial spores. Disinfectants are applied only to inanimate objects.

Disinfection: The inactivation of disease-producing microorganisms. Equipment/devices must be cleaned thoroughly before effective disinfection can take place.

- **High-Level Disinfectant (HLD):** The level of disinfection required when processing semi-critical medical equipment/devices. High-level disinfection processes destroy vegetative bacteria, mycobacteria, fungi and enveloped /non-enveloped viruses, but not necessarily bacterial spores.
- **Low-Level Disinfectant (LLD):** The level of disinfection required when processing non-invasive medical equipment (e.g., non-critical equipment) and some environmental surfaces.

Health Care Provider: An employee (including contracted individuals, students and volunteers) of PMH who provide direct care or indirect non-contact care as a result of their duties/tasks of their position. Health care provider spans the continuum of services/care that a client may receive from a PMH facility or program.

Health Care Setting: The facility or setting in which a client receives health care services within Prairie Mountain Health (PMH). Health Care Settings include but are not limited to Acute care, Transitional care, Personal Care Homes, Public Health Clinics, Therapy Departments, Assisted Living Facilities, Mental Health Facilities, Home Care Departments, Pre-Hospital settings, Surgical Facilities, Ambulatory Care Clinics etc.

Intended Purpose: The use for which a Medical Device is intended to be used according to information supplied by the Manufacturer on the labeling, instructions and/or promotional materials.

Limited Use: A medical device that is intended only for a specified number of uses by the Manufacturer and can be re-processed in accordance with Manufacturer's Guidelines in between uses. Examples include specific Respiratory Therapy equipment. The number of times each individual item can be, and is, reprocessed is documented and appropriate records of reuse are maintained. Controls and monitoring arrangements are to be in place to ensure that the agreed number of reprocessing episodes is not exceeded.

Manufacturer Guidelines/Instructions for Use: The Manufacturer is the person (includes partnerships, firms or associations) who sells a medical device under their own name or a trade-mark, design, trade name or other name and is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing, modifying or assigning the Medical Device an Intended Purpose. The Manufacturer provides written directions of a product that contain the necessary information for the safe and effective use of the product including the cleaning of the product.

Medical Device: Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, 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.

Medical Device Reprocessing: A centralized area within the health care setting for cleaning, disinfection and/or sterilization of medical devices.

Non-Critical Medical Device: Device that touches the client's intact skin (not mucous membranes) or does not directly touch the skin. These devices must be cleaned and may also require low-level disinfection (e.g. blood pressure cuffs, stethoscopes, mechanical lifts such as a Hoyer lifts).

Reprocessing: The steps performed to prepare used medical equipment/devices for use (e.g., cleaning, disinfection, sterilizing).

Semi-Critical Medical Device: A device that comes into contact with non-intact skin or mucous membranes and does not ordinarily penetrate them (e.g. trans-rectal probes, vaginal, nasal and rectal specula, respiratory therapy equipment (oral endotracheal tubes, airway devices, suction devices unless stipulated on the packaging to be single use only and cannot be reprocessed) . These devices must receive reprocessing involving meticulous cleaning followed by, at minimum, high-level disinfection.

Single Client Use Medical Device: A term given to medical equipment/devices (critical or semi-critical) that may be used on a single client and may be re-used on the same client, but may not be used on other clients. Examples include nebulizers, metered dose inhaler spacers, infant oxygen sensor, hard suction tips unless stipulated on the packaging to be single use only.

Single-Use Medical Device: A term given to medical equipment/devices (critical or semi-critical) designated by the Manufacturer for single-use only. Single-use equipment/devices must not be reprocessed. Single-use medical equipment/devices are usually labeled by the Manufacturer with a symbol  or may be labeled as disposable, consumable, not for re-use or do not re-use, discard after single-use, or do not use twice.

Spaulding Classification: The internationally accepted classification scheme which groups devices according to the risk of infection associated with the device; categorizing medical devices into Critical, Semi-Critical and Non-Critical.

Sterilization: A validated process used to destroy all forms of microbial life including bacteria, viruses, spores and fungi. This is the level of reprocessing required for critical medical devices and devices must be cleaned thoroughly before sterilization can occur.

PURPOSE

Health Canada, as the regulatory body, establishes parameters for all Manufacturers who design, label and seek to sell their products in Canada. Manufacturers decide how to design and label each medical device. Single-use medical devices that are licensed by Health Canada are intended by their Manufacturers to be used only once during a single procedure and are not to be disassembled, cleaned, reassembled and reused. When single-use medical devices are dissembled, cleaned, reassembled and reused the performance, safety, and efficacy of the medical device is jeopardized. As such, Manufacturers are not obligated to provide instructions for the cleaning and sterilization of single-use devices which are not supported for use on other clients in accordance with the Food and Drugs Act and Medical Devices Regulations.

Medical devices are assigned risk classification category based on the risk of infection involved with the use of the medical device on a client. The Spaulding Classification system defines three risk classifications of devices including critical medical devices, semi-critical medical devices or non- critical medical devices. Reprocessing of medical devices, which includes the cleaning, reconditioning, function testing and disinfection or sterilization, must ensure that the medical device can be used safely on another client and must be in compliance with Health Canada (Food and Drugs Act and Medical Devices Regulations), provincial and regional policies and standards.

POLICY STATEMENT

Prairie Mountain Health (PMH) is committed to client safety within the continuum of care provided by the region through programs and services. This policy provides direction for the safe use of single-use medical devices to prevent the transmission of microorganisms and injury to clients receiving services by PMH Health Care Providers.

In compliance with Health Canada Food and Drugs Act and Medical Devices Regulations and Manitoba Health and Healthy Living policy; Prairie Mountain Health does not support or condone the reprocessing or reuse of single-use medical devices on clients unless indicated within this policy.

All Health Care Providers must have the understanding and knowledge of single-use devices including the appropriate use of the single-use devices according to Manufacturer's labeling, product information and instructions. Single-use medical devices shall only be used on an individual client for a single procedure and must be discarded immediately after it has been used.

RESPONSIBILITIES

All Health Care Providers who as a result of the duties of their position, use or come in contact with a medical device (critical, semi-critical or non-critical) must:

- Be knowledgeable in the assigned risk class of the product.
- Be knowledgeable of whether the device is a single-use medical device, if it can be reused or if it has limited use.
- Not reuse any single-use device that:
    - is labelled as single use,
    - has labelling that is unclear as to whether it is single-use
    - has no Manufacturer's validated written reprocessing instructions
- Report concerns or incidents related to the use of a semi-critical or critical single-use medical device through the PMH Incident Reporting System.
- Refer to and follow the Cleaning and Disinfection of Medical Equipment/Devices (Critical, Semi-Critical and Non-Critical) (R.CS.IC.120). Medical Device Reprocessing staff additionally shall follow the Classifying Items and Identifying and Isolating Single Use Items (I-M-23) policy.

PROCEDURE

1. Single-use medical devices shall only be used on an individual client for a single procedure or intervention and then must be immediately discarded and not used on another client.
    a. Single-use medical devices that may be utilized for repeated interventions and are only for the individual client should be cleaned according to the Single Client Use Semi-Critical Medical Equipment/Device Resource document (PMH338).

2. Sterile single-use medical devices must be maintained as sterile until point-of-care use.

3. Single-use medical devices, which are labelled as "limited use" as per the Manufacturer's guidelines shall be discussed and addressed for use in consultation with Infection Prevention and Control and Medical Device Reprocessing Teams.

4. Opened but unused single-use medical devices must be discarded.

5. Single client use medical devices may be reused on the same client however shall not be reused on another client.

6. Single-use medical devices that come in contact with blood, tissue or bodily fluids shall not be reprocessed or reused but discarded.

7. Prior to using a single-use medical device that was purchased in a non-sterile state; the medical device shall be inspected and processed to the Manufacturer's validated written reprocessing instructions.

8. Single-use medical devices or reusable medical devices shall not be used if they are outdated according to the package listed expiry date.

9. Annually; any incidents reported through the PMH Incident Reporting System shall be reviewed by Quality and Patient Safety in collaboration with the Clinical Directors Committee.

RELATED MATERIAL

R.CS.IC.120, Cleaning and Disinfection of Medical Equipment/Devices (Critical, Semi-Critical and Non-Critical)

I-M-23, Classifying Items and Identifying and Isolating Single Use Items

REFERENCES

Cleaning and Disinfection of Medical Equipment/Devices (Critical, Semi-Critical and Non-Critical) (R.CS.IC.120); December 10, 2014, Prairie Mountain Health

Classifying Items and Identifying and Isolating Single Use Items (I-M-23); February 2, 2016, Prairie Mountain Health

Single Use Medical Devices; February 27, 2009, Assiniboine Regional Health Authority, QI-XVIII-698

Reuse/Reprocessing of Single Use Disposable Products; May 2005, Brandon Regional Health Authority, R.CS.610

Reuse of Single-Use (Disposable) Medical Devices; March 31, 2006, Parkland Regional Health Authority
Single-Use Medical Devices; May 1, 2012, Alberta Health Services

Single-Use Medical Devices; September 12, 2014, Covenant Health

Standards for Single-Use Medical Devices: As Applied to Critical and Semi-Critical Medical Devices; February 18, 2011, Government of Alberta

Best Practice Guidelines for Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices in B.C. Health Authorities; December 2011, B.C. Ministry of Health

Reprocessing of Single-Use Medical Devices: a 2015 Update; April 2015, Canadian Agency for Drugs and Technology in Health (CADTH)

Food and Drugs Act and Medical Devices Regulations; Health Canada