Operational Directives	WRHA Infection Prevention & Control Program	
	Single Use Medical Devices	Page 1 of 4
	Approval Signature:	**Supersedes:** February 2013
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1.0 PURPOSE:

1.1 To provide clarity on reprocessing of items identified as Non-Critical, Semi-Critical, or Critical Single Use Devices (SUD).

2.0 DEFINITIONS:

2.1 Critical Occurrence –

- Any occurrence involving serious harm to *employees, medical staff, volunteers, students, visitors, and other persons associated with the facility/community service, or to property, reputation or security*.
- Any occurrence that has the likelihood to negatively affect public confidence, credibility and trust, including potential media involvement or litigation.
- Any occurrence involving an unplanned or unexpected disruption in the delivery of health care programs or services which may result in increased risk to patients/clients/resident (excludes planned and mitigated service reductions).
- An emergency or disaster
- A significant public health event[02]

2.2 Healthcare facility/centre - Includes, but are not limited to, acute care hospitals/centres, emergency departments, rehabilitation hospitals/centres, mental health hospitals/centres, long-term care facilities/centres, and clinics.

2.3 Medical Device - as defined in the Medical Device Regulations (SOR/98-282) but non-exhaustively , 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 human beings for the purpose of: diagnosis, prevention, monitoring, treatment, or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability; investigation, replacement, or modification of the anatomy or a physiological process; or control of conception.
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but can be assisted in its function by such means[0]. Medical Devices fall into one of the following three classes:

2.3.1 Critical Medical Device - one that penetrates skin or invades normally sterile parts of the body (i.e., Medical Devices with blood contact, and/or invasive into sterile body cavities).

2.3.2 Semi-critical Medical Device – one that touches the mucous membranes during use (i.e., Medical Devices with mucous membrane contact or invasive into non-sterile body cavities).

2.3.3 Non-critical Medical Device – one that does not normally contact the person receiving care or body fluids (i.e., Medical Devices with either no direct patient contact or intact skin contact only).

All classes of Medical Devices are included in mandatory reporting by Healthcare Facilities (e.g. equipment, supplies and consumables) except Medical Devices regulated under Investigational Testing and Special Access Program framework that have separate reporting schemes in place.

2.4 Medical Device Incident (MDI) – an incident related to a failure of a Medical Device or a deterioration in its effectiveness, or any inadequacy in its labeling or in its directions for use that has led to the death or a serious deterioration in the state of health of a Patient, user, or other person, or could do so were it to recur. See mandatory reporting guideline. An assessment of causality is not required for a MDI to be reported through RL to the Canada Vigilance Program. Exemptions for reporting include where:

2.4.1 Deficiencies of devices would always be detected by the user, and where death or serious deterioration in health has not occurred.

2.4.2 Incident caused by a patient's condition.

2.4.3 Malfunction protection operated correctly.

2.4.4 Information is lacking regarding the name or identifier of the Medical Device or a description of a MDI.

2.5 Medical Device Reprocessing (MDR) Department – a functional area that reprocesses reusable Medical Devices (not necessarily centralized). In smaller health care settings, such as clinics or offices in the community, this refers to any segregated area where reprocessing of reusable Medical Devices takes place, away from patients. [0]

2.6 Manufacturer's Instructions For Use (MIFU) – written directions provided by the manufacturer or distributor of a product that contain necessary information for the safe and effective use of the product. Verbal instructions can assist the user in understanding the MIFUs, but they are not a substitute for written instructions. Ensure the MIFUs are correct for the product. Any questions or discrepancies regarding the appropriateness of the instructions must be resolved before the product is used. [Error! Reference source not found.]

2.7 Patient Safety Event – A general term referring to a near miss/good catch, occurrence, and critical incident, where an event or situation, resulted, or could have resulted, in unintended *harm to the patient, and/or damage to, or loss of, equipment or property*. [5.3]

2.8 Regional Medical Device Reprocessing Working Group – a group that facilitates and supports standardized quality reprocessing of medical devices; reviews, evaluates, and implements practices, standards, and evidence-based practices within Winnipeg facilities.

3.0 OPERATIONAL DIRECTIVES:

3.1 Items classified as Single Use Medical Devices (non-critical, semi-critical, or critical) (SUD) shall not be reused.

3.2 Medical Devices previously implanted shall not be reused.

3.3 Where reprocessing requirements are unclear or vague, requests shall be brought forward to the Regional Medical Device Reprocessing (RMDR) Working Group for review.

3.4 The Regional Medical Device Reprocessing Working Group shall:

3.4.1 Review the submitted request, MIFUs, standards, and other relevant materials as required to determine whether a SUD meets the outlined criteria for Reprocessing.

3.4.2 Communicate the decision of the RMDR team to the Healthcare Facility submitting the request.

3.4.3 Maintain an updated centralized list of SUDs reviewed through the RMDR Working Group.

3.5 When a SUD meets the outlined criteria for semi-critical or critical reprocessing, the Medical Device shall either be sent by the Healthcare Facility to a licensed third party reprocessing company for reprocessing, or picked up by the licensed third party reprocessing company for reprocessing.

4.3 In the event of any Patient Safety Event or Critical Occurrence that may be attributable to a reprocessed SUD, the Healthcare Facility shall:

4.3.1 Immediately notify the facility's Medical Device Reprocessing (MDR) Department;

4.3.2 Report the incident to the Regional Director, Medical Device Reprocessing;

4.3.3 Implement and document corrective action (Note: the Program Manager or designate has the authority to cease reuse of the Medical Device); and

4.3.4 Follow the Healthcare Facility's appropriate policy/procedure. .

4.3.5 Complete a product complaint form as appropriate.
Note 1: if there is a Patient Safety Event, complete and submit a RL6 report as well.
Note 2: if there is a Critical Occurrence, follow the Process for Reporting Critical Occurrences (Notification Form available here).

4.3.6 Evaluate the Patient Safety Event or Critical Occurrence against the criteria for the Mandatory reporting of Medical Device Incidents, Policy 110.000.490 to determine if additional reporting is required to the Canada Vigilance Program.

5.0 REFERENCES:

5.1 Canadian Standards Association (2018). Canadian medical device reprocessing CAN/CSA-Z314-18.

5.2 WRHA Critical Occurrence Reporting and Management policy. Available at: https://policies.wrha.mb.ca/policy/138/quality-risk-management-research-applied-learning/2968/10-50-045.pdf. Accessed July 13, 2022.

5.3 WRHA Patient Safety Events: Management of Occurrences, Near Misses and Critical Incidents policy. Available at: https://policies.wrha.mb.ca/policy/138/quality-risk-management-research-applied-learning/2972/10-50-020.pdf. Accessed July 18, 2022.

5.4 WRHA Medical Device Incident (MDI) Mandatory Reporting to Health Canada policy. Available at https://policies.wrha.mb.ca/policy/415/regional/3079/110-000-490.pdf. Accessed July 19, 2022.

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