Operational Directive	WRHA Infection Prevention & Control Program	
	Transportation, Distribution, and Storage of Contaminated, Clean and Sterile Medical Devices (on and off-site)	**Page 1 of 6**
	Approval Signature:	**Supersedes:** January 2013
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1. PURPOSE:

1.1 Minimize risk and increase safety for persons receiving care in relation to Transportation, Distribution, and Storage of Contaminated, Clean, and Sterile Medical Devices.
Protect persons receiving care, healthcare providers, and transport personnel from hazards associated with Transportation and Distribution of Contaminated Medical Devices.

2. DEFINITIONS:

2.1 Clean Medical Device – A Medical Device that is free from soil but has not been sterilized.
2.2 Contaminated Medical Device – A Medical Device containing pathogenic micro- organisms and is not safe to handle without personal protective equipment (PPE).
2.3 Decontamination – Cleaning, followed by inactivation of pathogenic microorganisms, to render an object safe for handling.
2.4 Distribution – The process of moving medical devices within a health care setting.[0]
2.5 Distribution Personnel – those responsible for the Distribution of Contaminated, Clean, or Sterile Medical Devices within facilities.
2.6 Event Related Sterility – a storage and transportation practice based on the principle that a properly packaged item that has successfully undergone a validated sterilization process is considered sterile until an event occurs that could breach the protection provided by the packaging (e.g., through wetting, tearing, or dropping). [0]

2.7 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[5.1]. Medical Devices fall into one of the following three classes:

- 2.7.1 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).
- 2.7.2 Semi-critical Medical Device – one that touches mucous membranes during use (i.e., Medical Devices with mucous membrane contact or invasive into non-sterile body cavities).
- 2.7.3 Non-critical Medical Device – one that does not normally contact with the person receiving care or body fluids (i.e., Medical Devices with either no direct contact or intact skin contact only).

2.8 Person Receiving Care (PRC) – Patient, Resident or Client

2.9 Routine Practices – A comprehensive set of IP&C measures that have been developed for use in the routine care of all PRCs at all times in all health care settings. Routine Practices aim to minimize or prevent healthcare associated infections (HAIs) in all individuals in the health care setting including PRCs, healthcare workers (HCWs), other staff, visitors, contractors, etc.[Error! Reference source not found.]

2.10 Sterile Medical Device – Medical Device free from viable microorganisms. [0]

2.10 Sterile Storage Area – designated area within Medical Device Reprocessing (MDR) or sterile procedures area (e.g. operating room) used for storage of sterile supplies.

2.11 Transportation – the movement of medical devices between an off-site facility and a health care setting. [0]

2.12 Transport Personnel – those responsible for the Transportation of Contaminated, Clean, or Sterile Medical Devices between facilities.

3. OPERATIONAL DIRECTIVES:

3.1 Transportation and Distribution of Contaminated, Clean or Sterile Medical Devices shall comply with the most current edition of CSA Z314.18 Canadian Medical Device Reprocessing standards.

3.2 Train personnel handling Contaminated, Clean, or Sterile Medical Devices (including off-site Transport Personnel), and document annual competency, in assigned functions as applicable, related to:

3.2.1 Principles of Infection Prevention and Control
- Personal hygiene and PPE/attire
- Hand hygiene practices, including method and frequency
- Occupational and Environmental Safety and Health requirements for their respective positions.

3.2.2 Handling of Sterile Medical Devices and supplies:
- Safe receipt of items
- Packaging and unpacking
- Event Related Sterility
- Inspection
- Principles of sterility and stock rotation.

3.2.3 Distribution and Transportation:
- Handling, Distribution and Transportation of Contaminated Medical Devices
- Handling, Distribution and Transportation of Sterile Medical Devices.

3.2.4 Record keeping retained for seven years.

3.2.5 Quality assurance.

3.3 Transportation

3.3.1 Contaminated Medical Devices:
- Transport in covered, fully enclosed containers designed to prevent spillage of liquids and allow decontamination after each use
- Schedule to allow immediate initiation of decontamination procedures
- Hold in a vehicle's compartment for holding Contaminated Medical Devices during Transportation that is environmentally controlled at a temperature between 20°C - 23°C and a relative humidity of 30%– 60%
- Clean and disinfect a vehicle's compartment that has carried Contaminated Medical Devices before Transportation of Clean or Sterile Medical Devices

3.3.2. Clean and Sterile Medical Devices:
- Transport in vehicles with pneumatic suspension to prevent damage
- Cover or contain during Transportation. Consider using further protection such as a 3-4 ml thickness dust covers that can be sealed
- Sterile instruments and supplies shall be transported separately from contaminated instruments, biohazardous waste, and garbage[5.3]
- Transport under environmental conditions indicated by the manufacturer if applicable

3.3.3 Distribution:

- Distribution Personnel shall perform hand hygiene as per Routine Practices.
- Distribution of Clean or Sterile Medical Devices and Contaminated Medical Devices shall not be on the same cart or handled by the same person simultaneously.
- Distribution and storage of Clean and Sterile Medical Devices shall be separate from Contaminated Medical Devices or soiled laundry
- Distribution carts shall have a solid base and be
  - Identified as carrying contaminated items
  - Covered or closed when outside the department. Exception: carts with a dedicated route ensuring there is no contact with other people or pieces of equipment
  - Wash covers after each use
  - Clean and disinfect carts between use.

3.3.4 Sterile Storage Area:

- Personnel and visitors in Sterile Storage Areas shall wear appropriate PPE/attire. Traffic shall be restricted in areas where sterile supplies are stored[5.3]
- Storage areas shall:
  - Keep windows closed
  - Keep doors closed when not in use.
- Be environmentally controlled:
  - Temperature between 15°C - 30°C
  - Humidity between 30% - 60%
  - Maintain positive pressure with air exchanges of 4 per hour
- Be closed to through traffic (if not possible, closed shelving required)
- Be close to sterilizing area, if applicable
- Be located away from areas for eating and drinking
- Be protected from:
  - Moisture and dust
  - Insects and vermin
  - Other contamination sources such as sinks and hoppers.

3.3.5 Shelving and containers:

- Shipping containers (i.e., corrugated cardboard boxes) shall not be:
  - Taken into Sterile Storage Areas
  - Used in an area where case carts are being picked
  - Used or stored in areas where clean or sterile items are stored.

- Shelving shall be:
  - Made of non-porous material
  - Non-shedding
  - Easily cleanable and free of rough edges
  - Constructed of a material that can be easily disinfected
  - Be a minimum of 2 inches (5 cm) from an outside wall
  - Be a minimum of 10 inches (25 cm) above the floor
  - Be 18 inches (45 cm) from the ceiling/sprinkler heads.
  - The top and bottom shelves of a shelving unit shall be impervious.
  - The use of solid plastic liners is appropriate for the top and bottom shelves
- Cleaning and disinfection of surfaces/areas shall be performed and documented as follows:
  - Counters cleaned daily
  - Shelves cleaned monthly
  - Floors cleaned daily
  - Walls cleaned every six months
  - Light fixtures, sprinkler heads and other fixtures every six months.

4. PROCEDURE:

4.1 Sites shall develop a procedure specific to the site, to operationalize above direction.

5. REFERENCES:

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

5.2 Routine Practices and Additional Precautions: Preventing the Transmission of Infection in Health Care. (2019, June). Manitoba Health, Seniors and Active Living

5.3 Operating Room Nurses Association of Canada (ORNAC). 2021. Standards, Guidelines, and Position Statements for perioperative registered nursing practice. 15th Edition.

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