Operational Directives	WRHA Infection Prevention & Control Program	
	Pre-Purchase Assessment of Multi-use Medical Devices (Instruments and Equipment)	**Page 1 of 5**
	Approval Signature:	**Supersedes:** February 2013
	Date of Approval: January 2023	
	Review Date: January 2025	

1. PURPOSE:

1.1 Provide the process that must be followed before purchasing a Multi-use Medical Devices.

1.2 Provide safe care during surgical and other invasive procedures.

2. DEFINITIONS:

2.1 Complex Medical Device – a Medical Device that contains one or several of the following areas which prove challenging to access with standard cleaning procedures: tight recessed cavities, threaded connections, meshing, sliding or mated surfaces, ball joints, lumens, components under tightly coiled spring tension, connections and joints between matted parts.

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

2.3 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. [5.1]

2.4 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:

2.4.1 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).

2.4.2 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).

2.4.3 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 contact or intact skin contact only).

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 care areas. [5.1]

2.6 Multi-use Medical Device – is a type of Medical Device that could be a Critical, Semi-critical or Non-critical Medical Device that is intended by its manufacturer to be used more than once on the same or different PRC as the manufacturer has deemed it suitable for reuse following manufacturer prescribed methods of disinfection or sterilization.

2.7 Person Receiving Care (PRC) – Patient, resident or client.

2.8 Reprocessing – Process of rendering a potentially contaminated Medical Device safe and effective for use on a patient. This includes cleaning, disinfecting, packaging, and sterilizing the Medical Device as required, and can include sharpening, repairing, re-lubricating, and recalibrating.

2.9 Sterilization - A validated process used to render a product free from viable micro-organisms.

3. OPERATIONAL DIRECTIVE:

3.1 Consultation with Medical Device Reprocessing (MDR) Department and Infection Prevention and Control (IP&C) shall occur for any Medical Device purchases where the device or its components require reprocessing (cleaning, disinfection and/or sterilizing). This operational directive applies to all purchases, including the repurchase of a device and/or when a substitute Medical Device is being considered.

3.2 Before purchase, Healthcare Facilities shall ensure they are supplied with validated, written MIFUs that is specific to the Medical Device, for:

- intended applications and limitations
- storage instructions before use
- maintenance of sterility and package integrity
- environmental conditions for transport and storage (i.e., temperature and humidity) and measures to be taken if these limits are exceeded
- evidence of sterilization processes used (if product purchased as sterile)
- use of the product, and
- presentation at the point of use.

3.3 Purchasing decisions for Multi-use Medical Devices shall involve representatives from the departments in the Healthcare Facility that will use, reprocess, and maintain the Medical Device.

3.3.1 Reviewing Departments shall include:

- MDR manager and/or delegate
- IP&C
- Unit or department personnel requesting the Medical Device, and
- Any other unit/department personnel who will also use the Medical Device

Note for items strictly used in the OR: these pieces will be assessed by MDR with IP&C consultation.

3.3.2. Other departments that may be involved include:

- Regional Clinical Engineering (RCE) or Site Clinical Engineering
- Risk Management
- Patient Safety
- Purchasing.

3.3.3 Prior to purchase of any new Multi-use Medical Device, there shall be confirmation the Medical Device:

- Is licensed according to Medical Device Regulations SOR/98-282. Verification of Medical Device License available at https://health-products.canada.ca/mdall-limh/index-eng.jsp in Canada
- Is being procured from a distributor with an establishment license if required by the Medical Devices Regulations (SOR/98-282), meeting applicable Canadian standards (e.g., written MIFUs, CAN/CSA-C22.2 No. 60601 series of Standards)
- Can be reprocessed by the Healthcare Facility
- The unit/department requesting purchase of the Multi-use Medical Device shall provide the MDR manager and/or delegate, and the site/area Infection Control Professional with the MIFUs for the Medical Device. This operational directive applies to all purchases, including the repurchase of a device and/or when a substitute medical device is being considered

-

3.3.4 For shared equipment/Non-Critical reusable Medical Devices refer to the Cleaning and Disinfection of Non-Critical Reusable Equipment/Items for Patients in Hospital.

3.3.5 For medical/surgical instrumentation the MDR manager and/or delegate at the Healthcare Facility in collaboration with IP&C and, where applicable, Regional Clinical Engineering (RCE) shall review the MIFUs to ascertain whether the instructions
- Are device specific, legible, and understandable
- Clearly indicate which parts need to be disassembled and provide clear disassembly instructions (including illustrations where necessary)
- Can be achieved, given the resources of the Healthcare Facility
- Are in accordance with the intended use of the Medical Device
- State whether or not the Medical Device is immersible
- Specify the necessary materials and equipment for sterilization or High-Level disinfection of the Medical Device
- Specify if there is a limit to the number of times the Medical Device can be reprocessed or if reprocessing will contribute to the degradation of the Medical Device
- Determine if disinfection and/or Sterilization can be achieved at the Healthcare Facility
- Specify methods of cleaning, including compatible cleaning and disinfection products, and
- Specify compatible Sterilization methods when required, including parameters for sterilization

3.3.6 Pre-purchase visual inspection by MDR, IP&C and, where applicable, the RCE shall be undertaken whenever possible

3.3.7 Whenever possible complex Multi-use Medical Devices shall be trialed prior to purchase

3.3.8 Multi-use Medical Devices should not be purchased if:
- It is determined that compliance with the MIFUs cannot be achieved, or
- It is determined compliance with the MIFUs for reprocessing the Multi-Use Medical Device is not sufficient to make the Medical Device safe enough for reuse and the MDR, IP&C and RCE departments cannot develop enhanced cleaning/sterilization/disinfection processes to make reuse safe.

3.3.9 If any of the departments involved have concerns with a Multi-use Medical Device and those cannot be resolved and there is no other Medical Device option, the physician shall:
- Discuss and review the risks with the PRC; and
- Obtain and document informed consent

3.4 Multi-use Medical Devices deemed to be donations or purchased privately must also follow the process for pre-purchase assessment as indicated in this operational directive.

4. PROCEDURE:

4.1 Sites shall develop a consultative process and implement the above purchase decisions requirements related to Multi-use Medical Devices and Medical Devices, where Medical Devices require reprocessing.

5. REFERENCES:

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

5.2 Alberta Health and Wellness. (2012). Standards for Cleaning, Disinfection and Sterilization for Reusable Medical Devices for all Health Care Facilities and Settings. Accessed October 21, 2019.

Operational Directive Contacts:
Molly Blake, Regional Lead, Medical Device Reprocessing