York Region
Infection Prevention and Control Lapse Report

,

Initial Report

Premise/Facility under investigation (name and address)

Pegasus Medical Clinic
1 Hesperus Rd Unit 201,
Thornhill, ON L4J 0G9

Type of Premises/Facility

Family Medicine Clinic

Date Board of Health became aware of IPAC lapse (yyyy/mm/dd)	Date of Initial Report posting (yyyy/mm/dd)
2022/02/01	2022/02/28
Date of Initial Report update(s) (if applicable) (yyyy/mm/dd)	**How the IPAC lapse was identified** Complaint

Summary Description of the IPAC Lapse

On November 12, 2021,York Region Public Health Unit conducted an inspection at the premise and noted inadequate reprocessing/sterilization of multi-use semi-critical medical equipment/devices. Detergent used for cleaning of multi-use semi-critical medical equipment/devices was expired and was not prepared and used according to manufacturer's instructions for use. The one-way work flow from dirty to clean was not always maintained to prevent cross-contamination of multi-use medical instruments; hand hygiene in the reprocessing area was being carried out in the same sink as manual cleaning of medical instruments; brushes used for manual cleaning of medical instruments were not replaced or adequality reprocessed; personal protective equipment (PPE) was not readily available for staff in the reprocessing area; and a log of the equipment that received sterilization was not kept.

IPAC Lapse Investigation	Yes	No	N/A	Please provide further details/steps
Did the IPAC lapse involve a member of a regulatory college?	☒	☐	☐	
If yes, was the issue referred to the regulatory college?	☒	☐	☐	College of Physicians and Surgeons of Ontario
Were any corrective measures recommended and/or implemented?	☒	☐	☐	

Please provide further details/steps	**Corrective measures:** • Discontinue the use of the Ritter M7 SpeedClave Sterilizer for the sterilization/reprocessing of medical equipment/devices. • Do not move or remove the above the Ritter M7 SpeedClave Sterilizer from the Premises until all necessary quality assurance records and tests have been conducted to determine that the autoclave is achieving sterilization. • Discontinue the use of any multi-use medical equipment/devices that were reprocessed in the Ritter M7 SpeedClave Sterilizer. These multi-use medical equipment/devices must be reprocessed in accordance with Provincial Infectious Diseases Advisor Committee (PIDAC) best practices. • Obtain three successful spore tests (using biological indicators) with the Ritter M7 SpeedClave Sterilizer conducted by an accredited third party: using the current process for sterilization and in accordance with the sterilizer manufacturer's instruction for use and provide the results to York Region Public Health **Prior to resuming sterilization of medical equipment/devices the operator must:** • Ensure that for all medical equipment/devices that require sterilization, a sterilization process used is in accordance with the "PIDAC Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in All Health Care Settings, 3rd Edition, May 2013". • Ensure biological indicator (BI) is placed in a process challenge device (PCD) with a Class 5 Integrator to test sterilizer each day the sterilizer is used and with each type of cycle used that day.

IPAC Lapse Investigation	Yes	No	N/A	Please provide further details/steps
				• Monitor and ensure a log of test results during sterilization is maintained and reviewed. Information to be recorded for every sterilization load and cycle includes: Load control label (sterilizer number, load number and date of sterilization); Chart/printout of physical parameters of the sterilization cycle; Load contents; Person responsible for the sterilization cycle; Chemical indicator (CI) monitoring results; and Biological indicator (BI) monitoring results. • Ensure medical equipment/devices are only released when the BI results are available; if quarantine pending BI results is not possible, operator to place a Class 5 or 6 Chemical Integrator in a process challenge device (PCD) within each load and the specific cycle physical parameters are used to justify the release of routine loads. • PPE is available and readily accessible in appropriate sizes in the reprocessing area. PPE (gloves, gown, mask, eye protection) is worn for procedures (e.g., instrument cleaning) that are likely to result in splashes and or sprays of blood or other body fluids. • Medical equipment/devices are packaged for sterilization in such a way that the steam can move around and through the item(s) and contact all surfaces and according to the MIFU for both the packaging and the medical equipment/devices. Medical equipment/devices are in the unlocked and open position for sterilization • Ensure the level of education, training, and certification of staff is based on the volume and complexity of the reprocessing activity, as determined by an organizational risk assessment • Demonstrate to the satisfaction of the Region's Medical Officer of Health that you are able to deliver sterilization/reprocessing of medical equipment/instruments in a safe manner using acceptable infection control practices.

Date any order(s) or directive(s) were issued to the owner/operator (if applicable) (yyyy/mm/dd)
2021/11/12

Initial Report Comments and Contact Information

Any additional Comments: (Please do not include any personal information or personal health information)

York Region Public Health provided an inspection report and a verbal order to the premise on November 12, 2021, outlining corrective measures to be implemented. Follow-up written order under the Health Protection and Promotion Act was issued on November 18, 2021. The premise indicated at the time they would use single-use disposable medical equipment/devices. Prior to resuming sterilization of reusable medical equipment/device the operator is to demonstrate to the satisfaction of the Region's Medical Officer of Health that they can deliver sterilization/reprocessing of medical equipment/instruments in a safe manner using acceptable infection control practices.

If you have any further questions, please contact
Health Connection

Telephone Number	Email Address
1-800-361-5653	Health.inspectors@york.ca

Final Report

Date of Final Report posting (yyyy/mm/dd)
2022/02/28

Date any order(s) or directive(s) were issued to the owner/operator (if applicable) (yyyy/mm/dd)
2021/11/12 – verbal order followed by issuance of a writer order on 2021/11/18

Brief description of corrective measures taken

At this time the premise is utilizing single-use disposable medical equipment/devices.

Date of all corrective measures were confirmed to have been completed (yyyy/mm/dd)

At this time the premise is utilizing single-use disposable medical equipment/devices.

Final Report Comments and Contact Information

Any Additional Comments: (Please do not include any personal information or personal health information)

If you have any further questions, please contact
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