York Region
Infection Prevention and Control Lapse Report

Initial Report

Premises/Facility under investigation (name and address)

Oak Ridges Aesthetics
401-13291 Yonge Street
Richmond Hill, Ontario L4E4L6

Type of Premises/Facility

Dermatology Clinic

Date Board of Health became aware of IPAC lapse (yyyy/mm/dd)	**Date of Initial Report posting (yyyy/mm/dd)**
2024/05/06	2024/05/27
Date of Initial Report update(s) (if applicable) (yyyy/mm/dd)	**How the IPAC lapse was identified**
	Complaint

Summary Description of the IPAC Lapse

- Concerns with reprocessing of multiuse medical devices/equipment.
- Sterilizer not currently licensed for use by Health Canada.
- Sterilizer parameters not monitored and log of test results during sterilization not maintained and reviewed.
- Biological Indicator (BI) and Class 5 Integrator not placed in a Process Challenge Device (PCD) to test sterilizer each day sterilizer is used.
- Records of physical parameters being met, not available on a print-out or data stick and Class 5 Integrator not placed in each medical equipment/device package/pouch that is sterilized.
- Concerns with following safe medication practices and Manufacturer's Instructions for Use (MIFU)
- Concerns with use of disinfectants, alcohol-based hand rub (ABHR) and hand soap

IPAC Lapse Investigation	**Yes**	**No**	**N/A**	**Please provide further details/steps**
Did the IPAC lapse involve a member of a regulatory college?	☒	☐	☐	College of Physicians and Surgeons of Ontario (CPSO)
If yes, was the issue referred to the regulatory college?	☒	☐	☐	
Were any corrective measures recommended and/or implemented?	☒	☐	☐	
Please provide further details/steps	**Corrective measures for Premises/Facility:** • Discontinue use of 'the current sterilizer' Midmark M7 SpeedClave for reprocessing multiuse medical devices/equipment. • Discontinue use of multiuse medical devices/equipment that were reprocessed in the Midmark M7 SpeedClave until sterilizations parameters of the Midmark M7 SpeedClave can be verified. • Reprocess (clean and sterilize) all multiuse medical devices/equipment after each use in accordance with the "Public Health Ontario: Guide to Infection Prevention and Control in Personal Service Settings, 3rd edition, First Revision: July 2019." • Label sterilized packages with date processed, sterilizer used, cycle or load number and the health care provider's initials in a manner that does not puncture or			

	dampen the package. If the medical device/equipment is not visible (e.g., wrapped cassette), label package contents.
	• Monitor sterilizer parameters and log test results.
	• Record sterilization load and cycle that include:
	  ○ Biological indicator (BI) results.
	  ○ Chart/printout of physical parameters of sterilization cycle.
	  ○ Load contents.
	  ○ Person responsible for the sterilization cycle; and
	  ○ Chemical indicator (CI) monitoring results.
	• Store sterilized wrapped packs/pouches in a clean, dry, dust-free area (closed shelves), not at floor level, away from debris, drains, moisture, sinks, and vermin to prevent contamination and maintain sterility until the time of use.
	• Check sterile medical devices/equipment for defects in the devices/equipment and discard if defects observed.
	• Follow Manufacturer's Instructions for Use (MIFU) for dispensing, using, labelling, and discarding of multi-dose vials.
	• Do not pre-fill syringes for later use.
	• Do not top up and use past their expiry date disinfectants, alcohol-based hand rub (ABHR) and medications.

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

Verbal Order Issued 2024/05/06. Written Order Issued 2024/05/15

- **Initial Report Comments:** Verbal Order was issued on May 6, 2024, this was followed up with a written Order on May 15, 2024. Operator discontinued the use of 'the current sterilizer' Midmark M7 SpeedClave for reprocessing multiuse medical devices/equipment. Operator discontinued using multiuse medical device/equipment that was reprocessed in the Midmark M7 SpeedClave, until multiuse medical devices/equipment were reprocessed following current best practices. Operator obtained three consecutive spore tests using Biological Indicators (BI) with the Midmark M7 SpeedClave using the current sterilization process.

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

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)

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

Brief description of corrective measures taken

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

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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