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)

2025/04/22

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

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 multi-use medical devices/equipment.

Brief description of corrective measures taken

Re-inspection was conducted on June 16, 2024. All corrective measures were implemented, and no concerns were noted at the time of re-inspection. The operator removed the Midmark M7 SpeedClave from the premises and demonstrated reprocessing of all multi-use medical equipment/devices after each use 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".The operator also demonstrated safe medication procedures in accordance with the "PIDAC Best Practices for Infection Prevention and Control for Clinical Office Practice April 2015" and Manufacturer's Instructions for Use (MIFU).

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

2024/06/16

Final Report Comments and Contact Information

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

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