

Initial Report

Premises/Facility under investigation (name and address)

Canada Vein Clinics
9555 Yonge Street, Suite 205,
Richmond Hill, Ontario L4C 1A3

Type of Premises/Facility

Vein Clinic

Date Board of Health became aware of IPAC lapse (yyyy/mm/dd)	Date of Initial Report posting (yyyy/mm/dd)
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2024/11/11

2024/12/04

Date of Initial Report update(s) (if applicable) (yyyy/mm/dd)	How the IPAC lapse was identified
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Referral

Summary Description of the IPAC Lapse

- Sterilizer not currently licensed for use by Health Canada.
- Non-compliance with adherence to the Manufacturer’s Instructions for Use (MIFU) and “PIDAC Best Practices for Infection Prevention and Control for Clinical Office Practice April 2015”, for the dispensing, using, and storing of multi-dose vials.

IPAC Lapse Investigation	Yes	No	N/A	Please provide further details/steps
Did the IPAC lapse involve a member of a regulatory college?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	College of Physicians and Surgeons of Ontario (CPSO)
If yes, was the issue referred to the regulatory college?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Were any corrective measures recommended and/or implemented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Please provide further details/steps

Corrective measures for Premises/Facility:

- Discontinue the use of ‘the current sterilizer’, EASYCLAVE Triumph TR250M, for reprocessing reusable medical devices/equipment.
- Discontinue the use of reusable medical devices/equipment that were reprocessed in the EASYCLAVE Triumph TR250 until sterilization parameters of the EASYCLAVE Triumph TR250 can be verified.
- Reprocess (clean and sterilize) all reusable medical devices/equipment 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”.
- Follow the Manufacturer’s Instructions for Use (MIFU) for dispensing, using, labelling, and discarding of multi-dose vials.
- Remove needles immediately from multi-dose vials once the medication is drawn up in accordance with the “PIDAC Best Practices for Infection Prevention and Control for Clinical Office Practice April 2015”.

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

Infection Prevention and Control Lapse Report

Verbal Order Issued 2024/11/11. Written Order Issued 2024/11/18

- **Initial Report Comments:** Verbal Order was issued on November 11, 2024, followed by a written Order on November 18, 2024. Operator discontinued the use of 'the current sterilizer' EASYCLAVE Triumph TR250 for reprocessing multi-use medical devices/equipment. Operator discontinued using multi-use medical devices/equipment that were reprocessed in the EASYCLAVE Triumph TR250. Operator obtained three consecutive spore tests using Biological Indicators (BI) with the EASYCLAVE Triumph TR250 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

1-800-361-5653

Email Address

Health.inspectors@york.ca**Final Report****Date of Final Report posting (yyyy/mm/dd)**

2025/04/17

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

Verbal Order was issued on November 11, 2024, followed by a written Order on November 18, 2024. Operator discontinued the use of 'the current sterilizer' EASYCLAVE Triumph TR250 for reprocessing multi-use medical devices/equipment.

Brief description of corrective measures taken

Re-inspections were conducted on December 17, 2024, and December 23, 2024. All corrective measures were implemented, and no concerns were noted at the time of re-inspections. The operator removed the EASYCLAVE Triumph TR250 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)

2024/12/23

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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