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1. What are Chemical Indicators (CIs)?

Chemical indicators (CIs) indicate that one or more physical process variables for sterilization have been met (e.g., time, temperature, pressure).

The CIs used most commonly in the oral health field are:

- **Class 1 CIs** respond to one or more critical process variables (typically on the outside of a package/cassette/pouch)
- **Class 4 CIs** respond to two or more critical process variables
- **Class 5 CIs** respond to all critical process variables.

Each instrument package/cassette/pouch **MUST** have a Class 1 CI on the outside and a Class 4 or Class 5 CI on the inside.

For full details, please review the *Instrument Preparation and Packaging* and *Sterilization* sections of the IPAC Standards

2. What are Biological Indicators (BIs)?

Biological indicators (BIs) use resistant spores in a vial which are incubated after being run through a sterilization cycle. A negative BI test confirms that these spores have been killed and, by extension, so have other potential pathogens in the load.

For full details, please review the *Sterilization Monitoring* section of the IPAC Standards.

3. What is a Process Challenge Device (PCD)?

A process challenge device (PCD) is also known as a “biological test pack”. It simulates an equal or greater challenge than the most difficult instrument/device set routinely processed for that sterilizer and/or cycle. It is placed in an area of the sterilizer known to be most challenging to achieve sterilization (as per manufacturer’s instructions).

There are commercially available PCDs, but they can be made in-office using decommissioned instruments and a BI in a package/cassette.

A test pack must be run at the beginning of each day you use the sterilizer. Follow the manufacturer’s instructions on *how* the test should be run For the PCD test packs, e.g., whether the test pack should be run on a full or empty load

Please refer to the full details starting on page 25 of the IPAC Standards.

4. When can Instruments in the Test Load and Other Loads be Used?

Instruments in the test load and each subsequent load must be quarantined (not used) until the result of the BI test comes back negative UNLESS a Class 5 indicator is used in each package/cassette/pouch.

Exception: All implantable devices and instruments used to place them must be sterilized using a BI (in each load) and cannot be used until a negative BI for that load is confirmed.

Please see the section on *Sterilization* for full details, starting on page 22.

5. Can I use Class 4 rather than Class 5 CIs inside each Package/Cassette/Pouch?

Yes, but the instruments MUST be quarantined (not used) until a negative BI result is confirmed for that sterilizer that day. In addition, at least one Class 5 CI MUST be used in each load.

The best practice is to use a Class 5 CI in each package/cassette/pouch.

Please review *Preparation and Packaging, Sterilization, and Sterilization Monitoring* for full details.

6. Is there a flowchart I can use to help me determine when I can release my packages?

Yes, with the permission of the PDBNS, the CDHNS has adapted their flowchart to assist you. You will find this in Registrant Portal as well, under the IPAC/COVID-19 tab.

7. Are Pouches with Integrated Internal Class 4 CIs Equivalent to Separately Inserted Class 4 CIs?

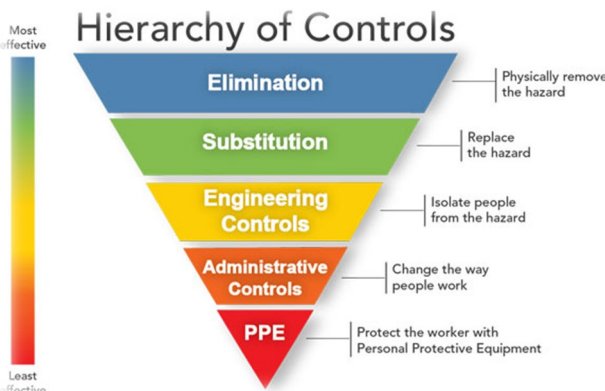
Yes. The PDBNS and CDHNS will accept these peel pouches as equivalent.

8. How do I minimize the risk of aerosols if I determine that it is appropriate to perform powered instrumentation?

Background: Powered instruments, such as ultrasonic scalers, have been shown to produce 3 times the bacterial aerosol contamination as that produced by the operative procedures performed by a dentist.¹ The decision to use powered instruments versus hand-scaling for dental hygiene periodontal debridement is based on evaluation of the client's specific oral health needs, any complicating dental or medical health factors, the amount and tenacity of deposits, periodontal pocket depths, and choosing the most effective therapy to obtain the desired client outcomes. Use of hand scaling only is not always the best option for a client. Therefore, the use of powered instrumentation must continue to be a therapeutic option for dental hygienists and dentists.

Use of powered instruments can be safe for both the client and the Dental Health Care Practitioner (DHCP) if appropriate strategies and protocols, including aerosol reduction techniques, are used. The USA Center for Disease Control and Prevention (CDC)'s guidelines for infection control in dental settings and the Canadian Standards Association (CSA) continue to support the use of techniques that significantly reduce aerosol generation, including the use of a high-velocity air evacuation and four-handed dentistry.

Using high-velocity air evacuation during dental treatment greatly minimizes dissemination of droplets, spatter, and aerosols. The high-volume evacuator (HVE) is the only high-velocity air evacuation device currently available. There are several risk mitigation methods that are to be integrated when you determine using powered instrumentation is necessary, following appropriate client screening.



<https://www.cdc.gov/niosh/topics/hierarchy/default.html>

Wear appropriate PPE (e.g., protective eyewear, correct level of masks, and client-specific gowns), in conjunction with using engineering and administrative controls. In addition to the pre-procedural rinse for clients whom it is not contraindicated, **integrate one of the two technologies/techniques.**

- Use high-volume evacuation with an adaptor, if RDH is providing care as a sole operator
- Use the four-handed technique*

For powered instrumentation, the goal is not merely water management; it is aerosol containment (reduction) and controlling the risk of disease transmission.

Attaching a saliva ejector to the HVE is not an acceptable option for reducing aerosols during powered instrumentation. Using a saliva ejector means that the unit becomes a low volume evacuator* (LVE). Saliva ejectors and isolation devices are appropriate for many different procedures (e.g., sealants).

However, they offer no protection from contaminated aerosols. Make the correct choice of your tool/technique based on the need e.g., isolation, water evacuation, or reduction of aerosols. As you

research alternative equipment options to the four-handed technique for powered instrumentation, refer to question 3 for further details on how to select an appropriate HVE adaptor option.

*Low-volume evacuators (LVE) remove a significantly lower volume of air. Air volume is measured in cubic feet per minute (CFM). While both HVEs and LVEs maintain the same static vacuum pressure, the difference in air volume is due to the bore hole size, or the number of holes in the evacuator tip.

Additional Reference for this question:

1. Grenier D. Quantitative analysis of bacterial aerosols in two different dental clinic environments. Appl Environ Microbiol. 1995;61(8): 3165-3168.

9. I will be using HVE on my own when performing AGPs that require its use. I know I need an adaptor. What adaptors do you recommend?

The CDHNS does not recommend specific adaptors. As the clinician, you must determine which HVE system is most effective for aerosol reduction while maintaining DHCP ergonomics, ease of use, and client comfort. The ergonomics and ease of use can be very operator specific.

Consider these elements to determine your best choice:

- **Confirm it is a registered medical device with Health Canada.** Is it a product that is registered for sale in Canada as an approved medical device for that purpose?
- **Evaluate the evidence on the adaptors you are considering** e.g., is it effective at reducing aerosols and does the use of the adaptor mean the unit still qualifies as an HVE? There are many devices on the market today that fit HVE ports but perform as LVEs. The standard HVE device used in the dental field has a large opening (~8 mm or greater) and is attached to an evacuation system that will remove a volume of air up to 100 cubic feet per minute.²
 - While both HVEs and LVEs maintain the same static vacuum pressure, the difference in air volume is due to the bore hole size, *or* the number of holes in the evacuator tip.
- **Confirm performance of your office's system:** Confirm that the power and suction volume of the HVE systems are performing safely and effectively.
- **Confirm usability to ensure appropriate performance:** For example, in order to work effectively, HVE devices need to be held approximately 6-15 mm away from the active powered instrumentation or air polisher. This means the unit cannot be stationed in one location in the client's mouth.
 - Can you move the adaptor properly so that you can place it in the appropriate position (e.g., consider weight and maneuverability)?
 - Can you move the suction within the mouth without causing discomfort (e.g., refrain from sucking up the client's cheek) while still maintaining your focus on the working field?
 - How will you manage reduced visibility?
- **Confirm if the product is reusable or single use disposable.** If it is reusable, confirm there are validated manufacturer's instructions for reprocessing. If there are none, they cannot be reused.
- **Consider the ergonomics of the adaptors:** What are the design elements that are important for you, as the operator e.g., weight of the unit, including the adaptor?

References for this question:

1. Bowen M, Pieren, J. Darby and Walsh: Dental Hygiene Theory and Practice, Fifth Ed. (2020). USA. Elsevier. ISBN: 9780323477192
2. Harrel SK, Molinari J. Aerosols and splatter in dentistry: a brief review of the literature and infection control implications. J Am Dent Assoc. 2004;135(4):429-437. doi:10.14219/jada.archive.2004.0207 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7093851/>
3. High-volume evacuation: Aerosols—It's what you can't see that can hurt you. (July 1, 2017). <https://www.rdhmag.com/patient-care/article/16409779/highvolume-evacuation-aerosolsits-what-you-cant-see-that-can-hurt-you> Retrieved: June 17, 2020.

10. What are Airborne Precautions?

Airborne precautions are used to prevent the transmission of pathogens by aerosols. **If it is deemed necessary to use airborne precautions, (e.g., client is COVID positive and treatment can't be deferred), the measures described below must be implemented.** If this is not possible, refer to a facility with the ability to provide care using these measures.

In the dental setting, these include the following:

- Fit tested N95 respirator or the equivalent (as approved by Health Canada)
- Eye/Face protection:
It is at the discretion of the DHCP as to what type of eye protection they choose to wear. The important concept - regardless of whether goggles, a face shield, or a combination of both are used - is that the PPE must protect the eyes of the DHCP from splatter, droplets, and aerosols that may be generated during the provision of dental care.
- Gown/lab coat — **it is strongly recommended that you use gowns that tie at the back during AGPs, rather than lab coats. If lab coats must be selected, in addition to long sleeves, preferable features include closures (snaps, buttons) that can be fastened and secured.**
- Gloves
- Settling times based on air changes/hour:

ACH	Time (min) required for removal 99.9%
2	207
4	104
6	69
8	52
10	41
12	35
15	28
20	21
50	8

* adopted from <https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html>

If a client requires airborne precautions, and your practice does not have floor to ceiling walls with doors, book the client at the end of the day when there are no other clients in the facility. If you are unsure what the air changes/hour are in your facility, allow for 207 minutes of settling time. Clean and disinfect the treatment room once the settling time has ended. *Alternatively, as noted above, refer the client to a facility that has the appropriate infrastructure in place to provide care using these measures.*