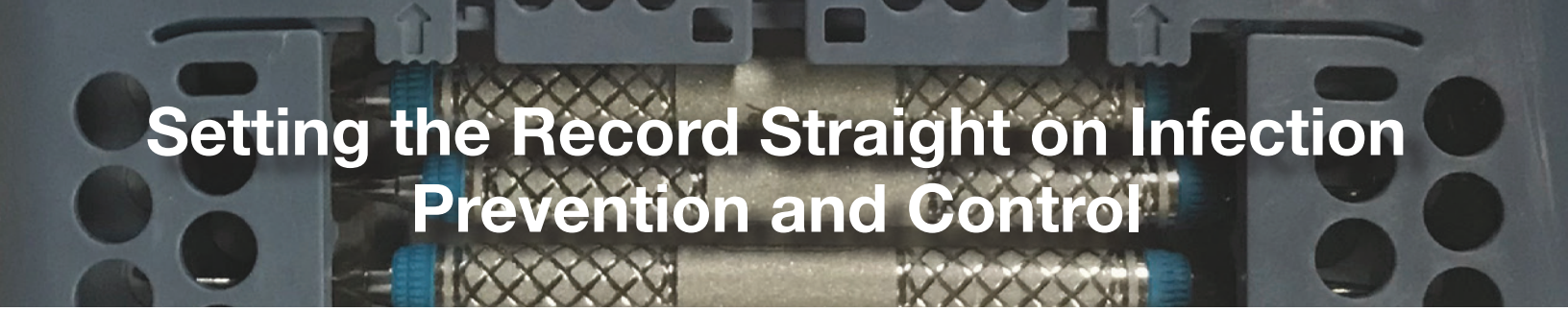

Setting the Record Straight on Infection Prevention and Control

The Facts About Steam Chemical Indicators

by **Giulia Galloro** RDH, BSc(DH)

In order to protect the public, the College has a code of ethics, regulations and standards of practice that ensures all dental hygiene clients receive the care they deserve. These standards of practice apply equally to all registrants, regardless of their practice setting. The CDHO expects all registrants to follow the most current standards and guidelines on infection prevention and control from the Public Health Agency of Canada, the Canadian Standards Association (CSA) and the Provincial Infectious Disease Advisory Committee (PIDAC). Every dental hygienist should have written policies in place that follow the most current evidence-based research on Infection Prevention and Control. Anyone involved in the infection prevention and control procedures, should be properly trained on how to use the reprocessing equipment in the office and be informed of the manufacturer's instructions on how to clean, disinfect and sterilize all equipment, instruments and medical devices used in their practice.

Every day, practice advisors at the College receive calls from dental hygienists and the public asking for clarification on what sterilization practices should be followed and how they should be monitored. This article will address one of the most common inquiries that the College receives pertaining to sterilization monitoring.

All sterilization processes must be monitored using physical, biological and chemical parameters. One of the most common inquiries that the College receives pertaining to sterilization monitoring is on the use of **steam chemical indicators**. For sterilization monitoring, the CDHO always recommends that you follow the manufacturer's instructions for the type of sterilizer you are using.

The CDHO expects all registrants to follow the most current standards and guidelines on infection prevention and control from the Public Health Agency of Canada (PHAC), the Canadian Standards Association (CSA) and the Provincial Infectious Disease Advisory Committee (PIDAC).

What the Dental Hygienist Needs to Know About Chemical Indicators

A Chemical Indicator (also referred to as a CI) is a monitoring system that responds to a change in one or more pre-defined variables, based on a chemical or physical change resulting from exposure to a process. There is no hierarchal significance in the classes of indicators (see Table 1 on page 10). The choice of indicators should be based on the parameters being measured, as each class has its own unique characteristics and intended use. For example, Class IV is not superior to Class I; they simply measure different variables.

Chemical indicators (internal and external) use sensitive chemicals to assess physical conditions such as time, temperature and presence of steam. Chemical indicators must be used on the inside and outside of **each** package to show that it has undergone a sterilization cycle. The colour change alone, indicating a passed test is not enough to prove that sterilization has been achieved. The person responsible for sterilization must check the physical, biological and chemical parameters to ensure the sterility of items has been achieved.

Chemical Indicators do not indicate that a device is sterile and should not replace the use of biological indicators.

- **External chemical indicators** are intended to indicate that the unit has been directly exposed to steam for a minimum amount of time and is used to distinguish between processed and unprocessed items. **Each plastic/paper pouch or wrapped cassette must have an externally visible Class I indicator.** Class I indicators respond to one or more critical process variables. One example of a Class I chemical indicator is indicator tape that is applied to the outside of a package and primarily used to secure wrapped cassettes of instruments. Once the **plastic/paper pouch or wrapped cassette** are removed from the sterilizer, the external chemical

indicator should have changed colour indicating the items were exposed to steam and processed.

- **Internal chemical indicators** respond to a change in one or more pre-defined process variables with a chemical or physical change. An internal chemical indicator must be placed in **each** plastic/paper pouch or wrapped cassette undergoing sterilization. Placement of the chemical indicator strip should be in an area judged to be least accessible to steam penetration. Placing an internal chemical indicator in each **load** is not sufficient. Rather, at **minimum an internal Class IV chemical indicator strip must be used, and placed inside each package**.

Class IV chemical indicator strips are multi-variable indicators and react to two or more critical variables in the sterilization cycle as specified by the manufacturer. When using Class IV chemical indicator strips, it is recommended that instrument loads are not used until the results of the BI spore test are known and have passed for that day. This may require between 12 and 24 hours of quarantined instruments after processing the BI, depending on the spore test being used. Internal Class IV chemical indicators are to be checked at the point of use, prior to using the instruments. Results must be recorded in a sterilization log book.

In the event that external or internal chemical indicators indicate inadequate processing, items in the package must not be used until after investigation, the problem is corrected and the package is successfully reprocessed.

What if it Is Not Possible to Quarantine Your Instruments?

If it is not possible to quarantine instruments until the biological indicator result is known, then the use of an internal **Class V chemical integrator indicator strip or Class VI emulating indicator must be placed inside every plastic/paper pouch or wrapped cassette** you wish to release. A Class V integrator strip reacts to time, temperature and steam and closely resembles the performance of the BI in saturated steam. Class VI emulating indicator strips react to time, temperature and steam for a specified cycle. A passed Class V or VI chemical indicator result and the physical parameters (time, temperature, pressure) being met, may be used to justify the immediate routine use of those instruments. Internal chemical indicators are to be checked at the point of use, prior to using the instruments. These results should be recorded in a sterilization log book.

*Class I external chemical indicators and Class IV internal chemical indicators, are the mandatory requirements for sterilization. If instruments cannot be quarantined until the biological indicator results are available, then at minimum an internal Class V or VI chemical indicator strip **must** be used.*

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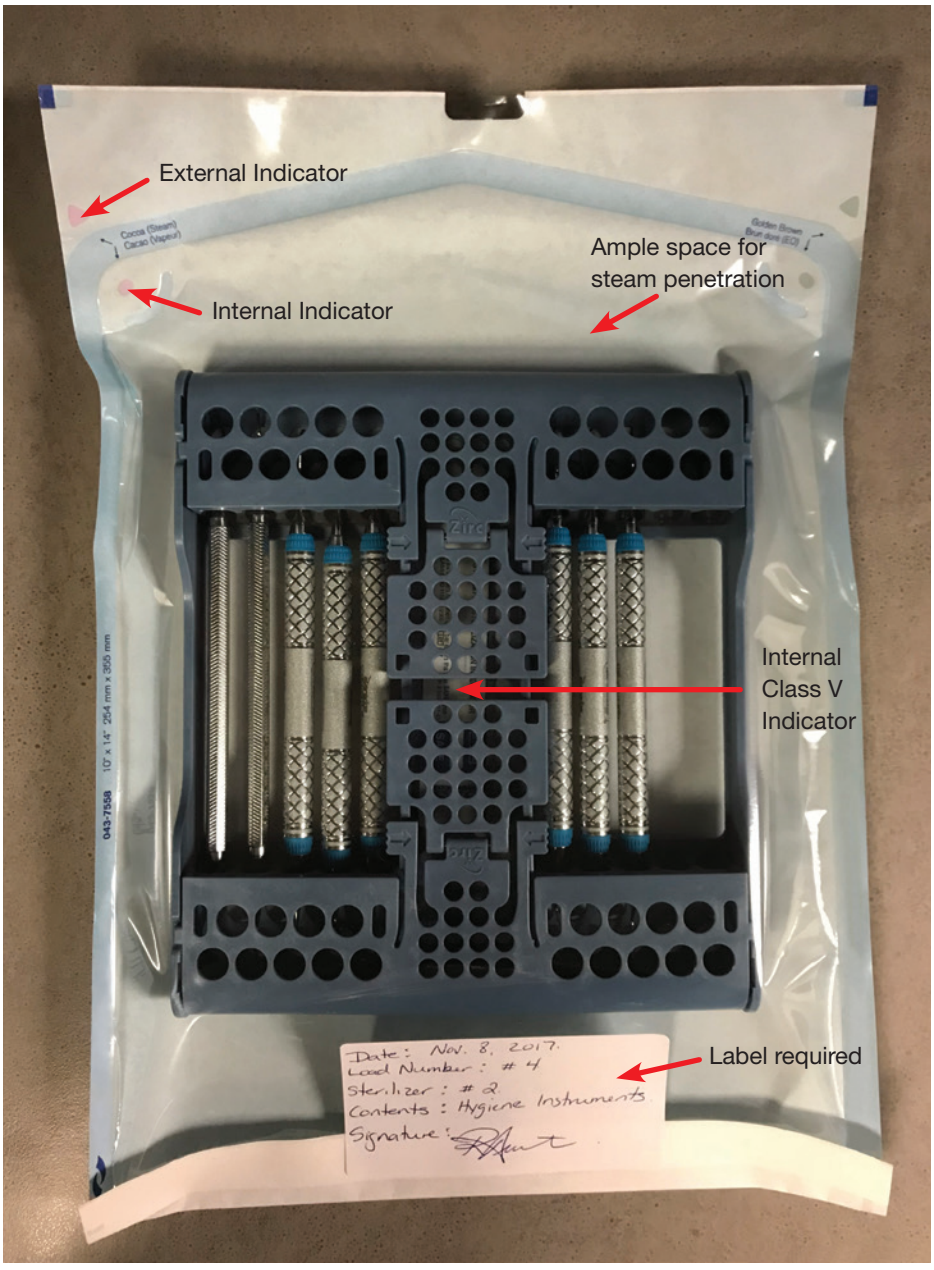

Why Use a Daily Biological Spore Test in Addition to Chemical Indicators?

Chemical indicators do not indicate that a device is sterile and should not replace biological indicators. The biological spore test is still the gold standard and the most accepted means for monitoring sterilization. The biological indicator test consisting of bacterial spores demonstrates the actual killing of an organism against a control test containing viable bacteria. A sterilizer should be tested (challenged) using a biological indicator each day the sterilizer is used as well as tested for each type of cycle (i.e. wrapped and plastic) that is used that day. These results must be recorded in the log book. In the event of a failed biological spore test, you would need to recall the instruments that were used on each client and determine the cycle, load and sterilizer affected.

A written protocol must be established to recall all improperly reprocessed devices and instruments. All items being reprocessed should be recorded and tracked in the event of a failed biological spore test.

Table 1: Classes of Chemical Indicators

Class	Description	Common Uses
Class I: Process Indicators	Used to differentiate processed from non-processed items	Responds to one or more critical process variables Usually applied to the outside of packages E.g. Peel back pouches usually have a chemical indicator manufactured on the paper side of the package and chemical indicator tape is also available
Class II: Specific Test Indicator	Indicator is used in specific tests or procedures to evaluate sterilizer performance Its purpose is to evaluate proper air removal from the sterilizer	To be used with dynamic air removal (pre-vacuum) sterilizer and should be performed each day the sterilizer is used E.g. Bowie-Dick Test
Class III: Single Variable Indicator	Reacts to a single critical process variable (i.e. temperature or time)	Exposure control monitoring in a specific location Rarely used in dental settings
Class IV: Multi-Variable Indicator	Indicator reacts to two or more critical variable in the sterilization cycle The manufacturer specifies the conditions under which the parameters are met	May be used for process control E.g. Indicator strips are manufactured inside on the paper side of the peel back pouches
Class V: Integrating Indicator	Responds to all critical variables in the sterilization process (i.e. time, temperature, presence of steam)	Used as an internal CI process control Responds to all critical variables in the same way that a BI responds May be used as an additional monitoring tool to release loads that do not contain implants E.g. Indicator strips
Class VI: Emulating Indicator	Indicator reacts to all critical variables (time, temperature and presence of steam) for a specified sterilization cycle (i.e. 10 min, 18 min, 40 min)	Used as an internal CI process control A different Class VI emulating indicator is required for each sterilization cycle time and temperature used May be used as an additional monitoring tool to release loads that do not contain implants

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices. 3rd ed. Toronto, ON: Queen's Printer for Ontario; May 2013.